UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
WASHINGTON, D.C. 20460

February 8, 2000

MEMORANDUM

SUBJECT: The revised Occupational and Residential Exposure aspects of the HED Chapter of the Reregistration Eligibility Decision Document (RED) for Vinclozolin, Case # 816411, PC Code 113201, DP Barcode D260678

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This revision to the occupational and residential risk assessment for vinclozolin was completed to incorporate data submitted to the Agency in a manner that reflects the most current Agency policies. The cancellation of stone fruit and strawberry uses and the restriction to greens and tees on golf courses are also addressed.

The following labels (identified by EPA Reg. No.) served as the basis for this assessment: 7969-57, 7969-62, 7969-85, CA83004400, CA89003000, SC90000500, and SC90000600. The Agency included all products associated with Reg. Numbers 7969-62 and 7969-85 as each has multiple end-use products. The section 24 C (SLN) labels were also evaluated in this risk assessment. Additional exposure scenarios added to the assessment based solely on the uses contained in a 24C label are noted on an individual basis.

The Agency has also recently received two Section 3 petitions for uses on snapbeans and canola. These uses have also been included based on the preliminary labels with the recent petition even though labeling has not been finalized for these products (i.e., they have no EPA Reg. Number at this time).

EXECUTIVE SUMMARY

Vinclozolin [3-(3,5-Dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione] is a dicarboximide fungicide that is marketed in a variety of end-use products. Vinclozolin formulations include: liquid flowable concentrates; dry flowables; and extruded granules (clay-based granules with vinclozolin embedded throughout the granular matrix not just on surface). Vinclozolin is used in agriculture on field crops (e.g., canola, lettuce, onions, snapbeans) and on fruit trees and small fruits (e.g., kiwi, raspberries) to control plant diseases such as bottom rot, purple blotch, and leaf blight. Vinclozolin can also be used in the ornamental/floriculture industry on woody and herbaceous ornamentals (e.g., azalea, crape myrtle, eumonymous, ficus, hydrangea, ivy, african violet, alyssum, aster, begoina, carnation, chrysanthemum), as a post-harvest cut flower dip or foliar spray (e.g., gladiolus spikes, roses, carnation, chrysanthemum, daisy, iris), as a dip for nurserystock (e.g., bulbs, corm, budwood, and barefoot nursery stock), and on turf (e.g., golf courses on tees/greens and on sodfarms) to control plant diseases such as anthracnose, brown rot, and helminthosporium (leaf spots and melting out). No products are available for sale to homeowners. Vinclozolin can be applied using a wide array of application equipment. In agriculture, groundboom, aerial, and airblast applications can be made. Other applications are completed using handheld equipment such as low pressure handwand sprayers, backpack sprayers, low pressure/high volume turfguns, and dipping tanks.

In light of these uses, exposures to vinclozolin can occur in the workplace (i.e., occupational exposures) and also to the general population (i.e., residential exposures). The Agency has considered both in this assessment. Occupational exposures can occur during the application process in agriculture and in the ornamental/floriculture market (i.e., referred to as handler exposures). These exposures involve individuals who complete all aspects of the application process including those who mix spray solutions (i.e., mixer/loaders), those who actually make the application (i.e., applicators), and those who direct aircraft while making aerial applications (i.e., flaggers). Occupational exposures can also occur as a result of entering previously treated areas to complete a job or task (i.e., referred to as postapplication exposures) such as harvesting, scouting, or maintenance/cultural activities. There are no products containing vinclozolin that are available for sale to homeowners. Therefore, the Agency did not consider handler exposures for the general population (i.e., referred to as homeowner handler exposures). Vinclozolin can, however, be occupationally used in a manner that can lead to exposures in the general population including those of golfers on treated courses and potentially through uses on sodfarms because of shipment and use in a residential environment. There is an extensive chemical-specific exposure database for vinclozolin that includes two handler exposure studies and nine postapplication studies on peaches, strawberries, and turf that measured human exposure as well as residue dissipation over time. Each of these studies have been used as appropriate in the development of this document. A variety of risk assessments have also been developed and submitted to the Agency by BASF Corporation, the registrant, that have been considered in this document. All of the occupational and residential exposures are considered to be short-/intermediate-term duration for the purposes of this risk assessment (i.e., 1 day up to 1 week and thereafter up to 180 days, respectively) as the same toxicological endpoint applies to this duration. In addition, since each of the exposure scenarios considered in the assessment occur at least sporadically, this places them in the short-term duration exposure category (see below). In very limited cases, exposures can also occur over extended periods of time that are chronic in nature (i.e., 180 working days or more per year) or of sufficient duration for the development of cancer. These extended exposures are only thought to occur in the ornamental/floriculture market and are not in agriculture.

The risk assessment has been revised to incorporate the recent decisions of the Agency's *Hazard Identification Assessment Review Committee* and *FQPA Safety Factor Committee*. In this assessment, separate toxicological endpoints/effects were identified for adult populations and children (i.e., infants and toddlers). Endpoints were also identified that apply to different durations of exposure as well as to the development of cancer and other noncancer effects. For adults (females 13+ are the target population), noncancer risk assessments (both occupational and residential) were completed for short-/intermediate-term exposures using a NOAEL of 3 mg/kg/day based on statistically significant decreases in male prostate weights from a pre-natal developmental toxicity study in rats (Gray 1996, MRIDs 44395701 and 44395702). For adults (the general population is considered), noncancer risk assessments (both occupational and residential) were completed for chronic exposures using a NOAEL of 1.2 mg/kg/day based on foam cell aggregates in the lungs (males), eosinophilic foci in the liver (males), interstitial cell lipidosis in the ovaries (females) and lenticular degeneration of the eyes (both sexes) from a chronic toxicity study in rats (MRIDs 43254701, 43254702, 43254703). Cancer risk calculations have also been completed in this assessment using both a threshold approach (i.e., cancer MOEs have been calculated) and a linear, low dose extrapolation approach using a Q_1*. The available mechanism data indicate that cancers will develop only after exposures of an extended duration so these calculations were completed for a very limited number of scenarios where exposures of an extended duration are expected to occur. When the linear, low dose extrapolation method was used in the cancer calculations, a Q_1* of 2.9×10^{-1} $(mg/kg/day)^{-1}$ based on moderate interstitial cell tumor rates in male rats has been used. When the threshold method was used, a NOAEL of 4.9 mg/kg/day has been used for the calculations. The level of concern for the Agency is established in the risk assessment process using uncertainty factors for MOE calculations and a quantitative population risk value for calculations using linear, low dose extrapolation. For the noncancer occupational risk assessments an uncertainty factor of 100 is used to account for inter-species extrapolation and intra-species variability. For the residential noncancer assessment for adults, the FQPA safety factor was retained, which has been applied in addition to the 100, indicating that the Agency's level of concern is 1000 for these scenarios. The Agency has not established a policy for defining uncertainty factors for cancer threshold calculations to date so these values are presented in the risk assessment for characterization purposes. The Agency has established a level of concern for cancer risks of 1×10^{-6} when the linear, low dose extrapolation method is used. A cancer risk value of 1×10^{-4} can be used if efforts are made in occupational settings to further mitigate risks. A dermal absorption factor of 25.2 percent, an inhalation absorption factor of 100 percent, and a body weight of 70 kg which is representative of the general population are used for all calculations.

The only exposures of children considered in this assessment are those related to the use of vinclozolin on sodfarms in which the exposures of toddlers were considered when defining the time required for vinclozolin residues to dissipate prior to the harvest of treated sod and placement into a residential environment. These exposures were all considered to be short-/intermediate-term in duration. For children, risk assessments were completed using a NOAEL of 5 mg/kg/day based on statistically significant decreases in preputial separation (a measure of puberty) from a post-natal developmental toxicity study in rats (Gray at October 1996 meeting of the FIFRA SAP). This endpoint has been applied to all exposure routes and was coupled with a dermal absorption factor of 25.2 percent, an inhalation absorption factor of 100 percent, and a body weight of 15 kg which is representative of toddlers in the general population. For the residential noncancer assessment for children, the FQPA safety factor was also retained as with adults. This factor has also been applied in addition to the 100 that accounts for inter-species extrapolation and intra-species variability, indicating that the Agency's level of concern is 1000 for these scenarios.

Based on the assessment of various exposure scenarios, the Agency has some risk concerns over the use of vinclozolin in both the agricultural and ornamental/floriculture marketplaces. When short-/intermediate-term occupational exposures are considered for handlers, risks in all exposure scenarios do not exceed the Agency's level of concern for both the agricultural marketplace and in the ornamental/floriculture marketplace (MOEs range from just over 100 to >10,000 depending upon the use scenario and level of personal protection). This result is based on requiring different levels of personal protection for each exposure scenario considered. Some low use/low exposure scenarios do not exceed the Agency's level of concern at the baseline level of personal protection which entails the use of normal work clothing represented by long pants and a long-sleeved shirt (e.g., mixing/loading granules for airblast application to raspberries). In other cases, however, more extensive personal protection is required such as the use of gloves, additional clothing, respirators, or engineering controls such as closed tractor cabs or water soluble packaging for solid formulations. Chronic occupational handler exposure scenarios were only considered for a very limited number of uses that are allowable in the ornamental/floriculture marketplace (e.g., foliar spray applied to cut flowers such as roses prior to storage/shipment). The risks in all of these exposure scenarios do not exceed the Agency's level of concern if chemical-resistant gloves are worn in addition to long pants and long-sleeved shirts during the application process (MOEs range from 212 to >10,000). For all occupational handler scenarios considered in the cancer risk assessment, MOEs ranged from approximately 20 to approximately 60, 000 at the baseline level of personal protection (i.e., long-sleeved shirts and long-pants only). At the most appropriate maximum levels of personal protection (i.e., engineering controls or double layer clothing, gloves, and respirator -- depending upon scenario), MOEs ranged from approximately 1400 to 5900 for the handheld application methods and from approximately 101,000 to 2.9M when water soluble packaging was considered for preparing dipping solutions. Population-based cancer risk estimates for all scenarios considered were less than $1x10^{-4}$ (indicating that the exposure did not exceed the Agency's level of concern) for all scenarios considered and in many cases were less than $1x10^{-6}$ depending upon the level of personal protection upon which the assessment is based. The only scenario for which cancer risks exceeded the Agency's level of concern for all levels of personal protection considered was for backpack sprayers when used to treat cut flowers with a foliar spray. This pattern was reflected in the results regardless of the annual exposure frequency considered in the assessment (i.e., a total of 90 days and a total of 180 days annual exposure were considered). The results of the risk assessment for handlers should be considered in the context that the vast majority of occupational vinclozolin handler exposures are thought to be of a short-/intermediate-term nature by the Agency. Therefore, it is believed that exposures do not exceed the Agency's level of concern for the vast majority of vinclozolin handler exposures.

The majority of concerns that Agency has over the use of vinclozolin stem from the occupational postapplication exposures considered in this assessment. Postapplication risks are mitigated by the Agency using an administrative mitigation measure which is referred to as the Restricted Entry Interval (REI) which represents the amount of time required for residues to dissipate in treated areas prior to beginning a job or task in that area with accompanying exposures that do not exceed the Agency's level of risk concern (e.g., an uncertainty factor of 100 for noncancer occupational risk assessments). For most of the uses in agriculture, risks do not exceed the Agency's level of concern within 30 days after application. [Note: All risks in agriculture are considered to be short-/intermediate-term in duration as with the agricultural handler scenarios.] For activities in low row crops such as scouting canola or lettuce the Agency believes that reentry into treated areas can occur (i.e., risks do not exceed the Agency's level of concern) 9 days after application. The Agency also believes that reentry can occur 21 days after application for activities such as harvesting lettuce, after 25 days for harvesting kiwi, and after 27 days for scouting and harvesting raspberries and low-growing snapbeans. The only occupational scenarios in agriculture where postapplication risks exceeded the Agency's level of concern for more than 30 days after application was for hand harvesting of onions and trellised snapbeans (38 days are required) which are believed by the Agency to be plausible, yet not a very common practice in agriculture.

The occupational postapplication risks for the ornamental/floriculture marketplace included a short-/intermediate-term, chronic, and cancer risk assessment. Short-/intermediate-term exposure calculations were completed for all scenarios while an assessment for chronic exposures and exposures of sufficient duration to cause cancer were only completed for a select number of scenarios. When short-/intermediate-term exposures are considered, risks for most uses do not exceed the Agency's level of concern within 30 days after application. For example, the Agency believes that mowing and maintaining treated turf can occur on the same day as application. The Agency also believes that reentry can occur 21 days after application for activities such as sorting and packing ornamentals in a greenhouse, after 27 days when irrigating ornamentals, and after 5 days for harvesting or placing sod. The only occupational scenario where postapplication risks exceeded the Agency's level of concern for more than 30 days after application was for cutting flowers in a greenhouse where 30 to 39 days were required for exposures not to exceed the Agency's level of concern. Chronic exposures were only considered for certain tasks associated with the production of ornamentals in a greenhouse. In all cases, the durations required for entry into a previously treated area was extended compared to the short-/intermediate-term assessment. When exposures are of a chronic duration, the Agency believes that reentry can occur 31 days after application for activities such as sorting and packing ornamentals in a greenhouse, after 37 days when irrigating ornamentals, and 39 to 48 days for cutting flowers in a greenhouse. For the postapplication cancer risk assessment, a maximum of 50 days after application was considered because durations longer than 50 days far surpass any logical proposal for establishing a viable REI. Given this premise, population-based cancer risks still exceed the Agency's level of concern even at 50 days after application for all activities considered including sorting/packing, irrigation, and cutting flowers (i.e., all risks were $> 1x10^{-4}$ for all scenarios considered even 50 days after application). Likewise, when cancer MOE values were calculated 50 days after application, these values were all <2000 for the same scenarios. As with the handler risks summarized above, the results of the risk assessment for postapplication workers in the ornamental/floriculture marketplace should be considered in the context that the vast majority of these exposures are thought to be of a short-/intermediate-term nature by the Agency. Therefore, it is believed that the results of the short-/intermediate-term risk assessment would be protective for mitigating most occupational postapplication risks.

Postapplication risks to the general population were only considered for golfers and for toddlers on sodfarm turf (in order to establish the amount of time required after application required for residue dissipation prior to harvest). All of these exposures are considered to be of a short-/intermediate-term nature by the Agency. Adult golfer exposures did not exceed the Agency's level of concern (i.e., an uncertainty factor of 1000) even on the day of application (MOE = 6800). Likewise, given the magnitude of the MOE for adults, the Agency also does not believe that risks for child golfers would exceed the level of concern. The aggregate MOE for toddlers on sodfarm turf (which represents an upper bound exposure that includes dermal and nondietary ingestion pathways) is 33 on the day of application. Risks do not exceed the Agency's level of concern until 24 days after application (MOE = 1096). If 2 days of transit time are allowed for sod harvest and placement, then treated sod cannot be harvested and placed into a residential environment for at least 22 days after application.

This assessment reflects the Agency's current approaches for completing residential exposure assessments based on the guidance provided in the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines (7/24/97 Version)*, the *Draft: Standard Operating Procedures (SOPs) for Residential Exposure Assessment (12/11/97 Version)*, and the *Overview of Issues Related to the Standard Operating Procedures for Residential ExposureAssessment* presented at the September 1999 meeting of the FIFRA Scientific Advisory Panel (SAP). The Agency is, however, currently in the process of revising its guidance for completing these types of assessments. Modifications to this assessment shall be incorporated as updated guidance becomes available and it is feasible from a regulatory perspective. This will include expanding the scope of the residential exposure assessments by developing guidance for characterizing exposures from other sources already not addressed such as from spray drift; residential residue track-in; exposures to farmworker children; and exposures to children in schools.

1. INTRODUCTION

This document incorporates the latest information pertaining to the fungicide vinclozolin. This includes the revised Report of the *Hazard Identification Assessment Review Committee* and the revised report of the *FQPA Safety Factor Committee*. A Q_1* has also been identified and applied only to longer-term exposures based on the available cancer mechanism data. Cancer *Margin of Exposure* values have also been calculated for characterization purposes.

The handler aspects of the assessment contain results for current federal labels, all SLN (Section 24C) labels, and the proposed new Section 3 labels for snapbeans and canola. Two handler exposure studies have been submitted in support of the registration of vinclozolin. The studies are part of the current data included in the Pesticide Handlers Exposure Database (Version 1.1). As such, the results from the individual studies have not been used individually to calculate risk values. Instead, the values have been used along with other similar PHED data to calculate unit exposure values per current Agency policy. These studies each also have a biological monitoring component. These biomonitoring data have not been used as they appear to be inconclusive for developing a quantitative risk assessment and there is a lack of acceptable supporting pharmacokinetic data. These data have, however, been used for risk characterization purposes.

An extensive database also exists with which to assess postapplication exposures (i.e., 9 studies on peaches, strawberries, and turf). Current vinclozolin labeling precludes direct application in a residential environment. However, vinclozolin use patterns can lead to exposures in the general population especially from golf course uses and potentially from the use of treated sod in a residential environment. As a result, a postapplication residential-style risk assessment has been completed for golfers and for sod farm uses. The golfer exposure/risk assessment that has been completed is based on the available turf transferable residue data and the standard approaches for calculating golfer exposure. The sod farm assessment has been completed in order to define the time required for vinclozolin residues to dissipate prior to harvesting and placement into a residential environment. The chemical- and scenario-specific turf transferable residue data and exposure data (generated using the Jazzercize approach) have been used as the basis for this assessment. Additional guidance, as needed, was taken from the *SOPs For Residential Exposure Assessment*. The Agency also completed occupational post-application risk assessments for several uses of vinclozolin in agriculture and in the ornamental/nursery market. Uses of vinclozolin on stone fruits and strawberries have been deleted and are not addressed in the current assessment. Some of the data, however, for these crops have been used to bridge to other crops such as lettuce or snapbeans in this assessment. Additionally, the registrant has proposed uses for two new crops (canola and snapbeans). These uses have been included in the assessment as appropriate. Risks from the use of vinclozolin in the ornamental/nursery market including cut flowers have also been calculated. Some of these scenarios are considered chronic exposures.

This memo was developed based on previous versions of the vinclozolin risk assessment and other information contained in a variety of documents included in the bibliography of this memo. Section 2 of this document contains the risk assessment and Section 3 contains the references used in the development of this document. All data and calculations are presented in various Appendices (A to H).

2. OCCUPATIONAL AND RESIDENTIAL EXPOSURE/RISK ASSESSMENT AND CHARACTERIZATION

The exposures and risks associated with the use of the fungicide, vinclozolin, that occur through non-dietary exposure are addressed in this section of the document. These exposures can occur as a result of applying vinclozolin or by entering areas that have been previously treated with vinclozolin such as agricultural fields. This chapter does not address possible vinclozolin exposures that occur through dietary intake of foods and water. Exposures can occur as a part of a job or through uses of vinclozolin in areas that are frequented by the general public. Occupational and residential exposures are addressed separately in this document.

Risk is defined in the *U.S. EPA Guidelines for Exposure Assessment* (U.S. EPA, Federal Register Volume 57, Number 104, Friday May 29, 1992) as the probability of deleterious health or environmental effects. *Risk assessment* can be described as the process that defines the *risk*. The *risk assessment* process has four major components including: exposure assessment, hazard identification, evaluation of the dose response, and characterization of the calculated risk values. This document addresses the exposure assessment and risk characterization aspects of the process. The hazard identification and evaluation of dose response are addressed in separate documents.

Use patterns and available products are summarized in a manner appropriate for nondietary risk assessment in *Section 2a: Use Pattern and Available Product Summary For Exposure Assessment*. The exposure/risk assessments that have been completed for each handler and postapplication scenario, for which appropriate data exist, are included in *Section 2b: Occupational and Residential Exposure/Risk Assessment.* The characterization issues associated with, and a summary of the results of each assessment, are included in *Section 2c: Occupational and Residential Risk Characterization*.

a. Use Pattern and Available Product Summary For Exposure Assessment

Vinclozolin products are described in this section. Additionally, available information that describes the manner in which vinclozolin products are applied is provided in this section (e.g., use categories/sites, application methods, and application rates). This section specifically includes a description of the available products that contain vinclozolin (*Section 2.a.i: Manufacturing- and End-Use Products*); the mode of action of vinclozolin and the pests that it is labeled to control *(Section 2.a.ii: Mode of Action and Targets Controlled*); a description of the crops/groupings and other areas on which vinclozolin can be used *(Section 2.a.iii: Registered Use Categories and Sites*); and a description of the manner in which vinclozolin can be applied (*Section 2.a.iv: Application Parameters*). All uses that have been deleted at this point will no longer be considered in this assessment (stone fruit and strawberries are examples).

i. Manufacturing- and End-Use Products

Vinclozolin [3-(3,5-Dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione] is a dicarboximide fungicide that is marketed in a variety of end-use products. Vinclozolin formulations include: liquid flowable concentrates; dry flowables; and extruded granules (clay-based granules with vinclozolin embedded throughout the granular matrix not just on surface). Based on a review (11/8/99) of the *Office of Pesticide Programs* --

Reference Files System(REFS), there are 6 active product labels and 10 products. The distribution of these labels and products is as follows: 1 technical label/product, 2 Section 3 labels for 6 distinct end-use products, and 3 State and Local Need (SLN or 24C) labels/products. There are also 2 preliminary labels associated with petitions that are pending for obtaining tolerances for snapbeans and canola. These pending uses are addressed in the risk assessment but are not summarized in the table below as no EPA Reg. No. has been assigned to date. The following table summarizes all active labels:

Formulation Type	Packaging	Percent Active Ingredient	EPA Reg. Numbers
Technical Grade	bags	96 & 50	7969-57
Flowable Concentrates	liquid containers	41.3*	7969-62 (includes Ronilan FL+ and Curalan) & SC90000600
Dry Flowables & Extruded Granules	water soluble bags or bags	50.0	7969-85 (includes Curalan DF, Curalan EG+, Ronilan DF, and Ronilan EG), CA83004400 , CA89003000

* = approximately 4.17 pounds of active ingredient/gallon

\+ = Curalan EG label is 1998 version not officially accepted ("stamped") by the Agency and Ronilan FL label is June 21, 1995 version that has not been revised to remove stone fruit and strawberries (these are not included in risk assessment, information for other crops from label used, however)

Vinclozolin products are marketed for occupational uses but not for homeowner uses. Occupational products are intended for use in the following markets: agriculture, ornamentals, and uses on turf in areas not frequented by the general public. There are no products intended for sale to homeowners.

ii. Mode of Action and Targets Controlled

Vinclozolin is a dicarboximide fungicide used for the control of many types of pests including:

- **In Agriculture:** bottom rot, purple blotch, leaf blight, neck rot, watery soft rot, and white rot on canola, lettuce, raspberries, onions, and snapbeans (also for kiwi fruit and chicory root/endive for the available Section 24C labels); and

- **On Ornamentals:** anthracnose, blossom blight, brown patch, brown rot, corn rot, dollar spot, flower blight, fusarium patch, pink snow mold, gray mold, gray snow mold, helminthosporium (leaf spots and melting out), pink thatch, and red thread.

iii. Registered Use Categories and Sites

An analysis of current vinclozolin uses was completed using available labels, the *Office of Pesticide Programs -- Label Use Information System, REFS*, and the recent *Quantitative Usage Analysis*. Vinclozolin is registered for use in a variety of occupational use scenarios but not for any residential/homeowner uses.

Occupational Use Sites: Individuals are potentially exposed on the job while making vinclozolin applications in agriculture and while treating ornamentals. Exposures can also occur as a result of entering previously treated areas and performing a task that can lead to exposure such as harvesting. Exposures can occur during application or after contact with the following:

Agricultural Crops Include:

- **Field Crops:** canola, lettuce, onions, snapbeans, and chicory root/endive (Section 24C label only for chicory);
- **Fruit Trees:** kiwi fruit (Section 24C label only);
- **Small Fruit:** raspberries.

Ornamental Use Sites Include [Note: List not inclusive, example plants presented]:

- **Woody ornamentals (Foliar Spray):** almonds (flowering varieties), azalea, carnellia, cedar, choke cherry, ornamental cherry, crape myrtle, elm, eumonymous, ficus, fir, hydrangea, ivy, juniper, pine, plum, poinsettia, redwood, rhododendron, and spruce;
- **Herbaceous ornamentals (Foliar Spray):** african violet, alyssum, aster, begoina, carnation, chrysanthmum, columbine, daffodil, delphinium, dieffenbachia, Easter lily, fuschia, geranium, hyacinth, impatiens, iris, ivy, marigold, narcissus, phlox, primrose, snapdragon, tulip, violet, and zinnia. [Note: List is not all inclusive of all labeled plants.];
- **Post-harvest cut flower (Dip):** gladiolus spikes and roses before cold storage or transit;
- **Post-harvest cut flower (Foliar Spray):** alstromeria, carnation, chrysanthemum, corn flower, daisy, iris, statice, and sweet William in cold storage or transit;
- **Bulbs and corm (Dip):** gladiolus, hyacinth, iris, lily, narcissus, and tulip;
- **Budwood and barefoot nursery stock:** roses (no other variety restrictions noted); and
- **Turfgrass:** No variety restrictions noted. No direct uses in residential areas. Uses on golf courses (tees and greens) and sodfarms are allowed.

Homeowner/Residential Use Sites: Significant residential (non-occupational) exposures are not expected except in a few limited scenarios. This is because there are no products that are labeled for purchase and use by homeowners. Additionally, the available labels for ornamentals and turf specifically preclude the direct occupational use of vinclozolin in residential settings. For example, the label for Curalan (EPA Reg. # 7969-62) indicates:

> "This product is not intended for residential use. This product may only be used as follows:
>
> **Commercial:** lawn and landscape areas at business and office complex sites, and turf at professional sport complexes or arenas; ornamental bedding plants.
>
> **Industrial:** lawn and landscape areas at manufacturing sites; ornamental/bedding plants.
>
> **Golf Course:** tee boxes, greens and turf mowed at 1" or less.
>
> **Greenhouse and Nursery:** greenhouses and nurseries associated with the production of plants for commercial purposes.
>
> **Sod Farms:** mechanically harvested turf only."

The Agency agrees that these label restrictions will significantly lower the potential for exposures in the general population. However, even given these restrictions, the Agency identified two scenarios that may potentially lead to an exposure event in the general population including: (1) treated turf harvested from a sod farm and transported/used in a residential setting, and (2) exposure to golfers from contact with treated greens and tees. These two exposure scenarios have been included in this risk assessment.

iv. Application Parameters

Application Parameters is a generic term that describes the factors that are considered in the development of a risk assessment in relation to how a chemical is applied, how much is applied, and how often it is applied. These parameters are generally defined by the physical nature of the use site, how a product is formulated (e.g., form and packaging), by the equipment used to make the application, and by the application rate required by the label. Vinclozolin is a fungicide that can be used in a variety of markets. Therefore, the application parameters are quite varied. These parameters are presented below for each major market and specific crop/target (e.g., application rates and the equipment that can be used to make applications). [Note: Average application rates have been supplied in the 11/3/99 version of the Quantitative Usage Analysis. These rates have, for the purposes of this risk assessment, been used as typical application rates in order to provide for a more informed risk management decision.]

Agricultural Crops Include:

- **Field Crops (canola, lettuce, onions, snapbeans):** This summary is based on the revised QUA (Quantitative Usage Analysis) of 11/3/99 and the following labels: Ronilan DF (EPA Reg. No. 7969-85); Ronilan EG (EPA Reg. No. 7969-85); and Ronilan FL (EPA Reg. No. 7969-62). [Note: The submitted petitions for canola and snapbeans are also summarized here to obtain information for canola and snapbeans.] Vinclozolin is used on these crops to control a variety pests throughout the growing season as noted above. The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre on lettuce; from 0.75 to 1.0 pounds of active ingredient per acre for onions; from 0.33 to 0.45 pounds of active ingredient per acre for canola; and 0.5 pounds of active ingredient per acre for snapbeans. Maximum application rates vary based on pest pressure and the timing of application. Typical application rates are 0.4 lb ai/acre for canola; 0.5 lb ai/acre for snapbeans and onions; and 0.8 lb ai/acre for lettuce (11/99 QUA). The formulations that are available include extruded granules and dry flowables that are dissolved in water and sprayed as a liquid. A liquid flowable formulation also exists that is addressed in this assessment but is being phased out based on BASF Technical Bulletin 9823. Application equipment includes airblast, aerial, chemigation, and groundboom (lettuce dipping is prohibited). Airblast applications are unlikely for all crops except snapbeans where tied plants may be treated. Chemigation is plausible for all crops and is allowable by the EG and DF labels but is expressly prohibited in the FL label. Broadcast (foliar) sprays are typically completed with a minimum of 50 gallons per acre using ground equipment and up to 20 gallons per acre by air. The first application to onions can also be banded (50 gallons per acre) or by soil drench (400 gallons per acre). The maximum seasonal application rate is 0.45 lb ai per acre for canola; 3 lb ai per acre for lettuce; 5 lb ai per acre for onions; and 1.0 lb ai per acre for snapbeans. Likewise, the typical seasonal application rate is 0.4 lb ai per acre for canola; 0.9 lb ai per acre for lettuce; 1.0 lb ai per acre for onions; and 0.6 lb ai per acre for snapbeans. Canola can be treated 1 time per season (11/99 QUA reflects this pattern). The application may begin a week after the first blossoms appear (e.g., 1 to 16 open blossoms on the main stem for Polish canola). Lettuce can be treated up to 3 times per season with the first application occurring immediately after thinning for direct-seeded lettuce or 7 to 10 days after transplanting. Subsequent applications cannot occur for 14 days. Typically, lettuce is treated 1.1 times per season (11/99 QUA). Onions can be treated up to 5 times per season (based on the maximum application rates) with the first application occurring at planting or post-emergence depending upon the pest. Subsequent applications cannot occur for 14 days. Typically, onions are treated 2.0 times per season (11/99 QUA). Snapbeans can be treated up to 2 times per season with the first application occurring at blossom. Subsequent applications may be required at full bloom or 7 to 21 days after the first application. Typically, snapbeans are treated 1.1 times per season (11/99 QUA). The PHI (pre-harvest interval) is 28 days for lettuce and 18 days for onions.

C **Field Crops (chicory/endive - Section 24C label only):** This summary is based on the revised QUA (Quantitative Usage Analysis) of 11/3/99 and the following label: Ronilan DF (SLN CA890030 of EPA Reg. No. 7969-85). Vinclozolin is used on these crops to control a variety pests on the chicory root portion of the plant either in cold storage or while forcing plants. For cold storage, the maximum single event application rate is 10 grams of active ingredient applied in 20 liters of water per metric ton of roots. During the forcing process, the maximum single event application rate is 1 gram of active ingredient in 3 liters of water per square meter of forcing tray surface area. The 11/99 QUA had no information on typical application rates. The formulation is a dry flowable that is dissolved in water. Application equipment, prior to cold storage, likely includes handheld equipment such as low-pressure handwands or backpack sprayers. During forcing, the application equipment is assumed to be propagation trays as described in the SLN label. The use of chemigation equipment is specifically prohibited. The label indicates that applications can occur prior to cold storage of roots and/or prior to forcing. Therefore, the maximum seasonal application rate is additive of the two kinds of applications and can be less if only one type of application is completed. The 11/99 QUA had no information on the typical use practices related to this crop. The PHI (pre-harvest interval) is 30 days.

• **Fruit Trees (kiwi fruit - Section 24C label only):** This summary is based on the revised QUA (Quantitative Usage Analysis) of 11/3/99 and the following labels: Ronilan DF (SLN SC900006 of EPA Reg. No. 7969-85) and Ronilan FL (SLN CA 830044 of EPA Reg. No. 7969-62). Vinclozolin is used on kiwi to control a variety pests throughout the growing season as noted above. The maximum single event application rate is 1.0 pound of active ingredient per acre. The typical application rate is 0.9 lb ai/acre for kiwi (11/99 QUA). The formulations that are available include a dry flowable that is dissolved in water and sprayed as a liquid and a liquid flowable formulation that is addressed in this assessment but is being phased out based on BASF Technical Bulletin 9823. Application equipment includes airblast sprayers. The maximum seasonal application rate is 4 lb ai per acre. Likewise, the typical seasonal application rate is 1.2 lb ai per acre. Kiwis can be treated up to 4 times per season with the first application occurring "mid to end of bloom." The three subsequent applications occur as follows: 8 to 10 days following the first spray; 7 to 14 days prior to the final spray; and at least 7 days prior to harvest. Typically, kiwis are treated 1.3 times per season (11/99 QUA). The PHI (pre-harvest interval) is 7 days.

- **Small Fruit (raspberries):** This summary is based on the revised QUA (Quantitative Usage Analysis) of 11/3/99 and the following labels: Ronilan DF (EPA Reg. No. 7969-85); Ronilan EG (EPA Reg. No. 7969-85); and Ronilan FL (EPA Reg. No. 7969-62). Vinclozolin is used on these crops to control a variety pests throughout the growing season as noted above. The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. Maximum application rates vary based on pest pressure and the timing of application. The typical application rate is 0.6 lb ai/acre for raspberries (11/99 QUA). The formulations that are available include extruded granules and dry flowables that are dissolved in water and sprayed as a liquid. A liquid flowable formulation also exists that is addressed in this assessment but is being phased out based on BASF Technical Bulletin 9823. Application equipment includes airblast, aerial, chemigation, and groundboom. Chemigation is plausible and is allowable by the EG and DF labels but is expressly prohibited in the FL label. Broadcast (foliar) sprays are typically completed with a minimum of 50 gallons per acre using ground equipment and up to 20 gallons per acre by air. The maximum seasonal application rate is 4 lb ai per acre. Likewise, the typical seasonal application rate is 1.2 lb ai per acre. Raspberries can be treated up to 4 times per season (based on the maximum application rate) with the first application occurring "no later than 10% primary bloom." Subsequent applications cannot occur for either 7 or 10 days (depending upon ambient moisture levels) throughout the bearing cycle. Typically, raspberries are treated 2.0 times per season (11/99 QUA). The PHI (pre-harvest interval) is 9 days.

<u>Ornamental Use Sites Include [Note: see above for specific examples of treated plants]:</u>

- **Herbaceous and woody ornamentals (Foliar Spray):** This summary is based on the revised QUA (Quantitative Usage Analysis) of 11/3/99 and the following labels: Curalan DF (EPA Reg. No. 7969-85); Curalan EG (EPA Reg. No. 7969-85); and Curalan (EPA Reg. No. 7969-62). Vinclozolin is used on many types of ornamentals to control a variety pests throughout the growing season as noted above. Applications can be made outdoors or in greenhouses. Applications are made either as a preventative or as a curative to control ongoing pest problems. The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). For preventative treatments, the spray concentration ranges from 0.0025 to 0.00375 lb ai/gallon and, for curative treatments, the spray concentration ranges from 0.00375 to 0.0050 lb ai/gallon. Each of the available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Apply until leaves glisten, but not to the point of run-off." The labels also indicate to "reapply every 10 to 14 days as needed" and to "use only on non-bearing plants." Application equipment includes aerial, airblast, groundboom, and a variety of handheld methods including low pressure handwands, high pressure handwands, and backpack sprayers. Airblast applications are unlikely except for certain trees and larger shrubs. The Agency also believes that aerial applications to ornamentals are unlikely except in large propagation facilities. Chemigation is expressly prohibited in each label. The maximum seasonal application rate is 4 lb ai per acre. No information was provided in the recent QUA (11/99) that provided information on typical application rates (i.e., including both single application events and on a seasonal basis).

C **Herbaceous and woody ornamentals (Thermal Fogging):** This summary is based on the revised QUA (Quantitative Usage Analysis) of 11/3/99 and the following labels: Curalan DF (EPA Reg. No. 7969-85); Curalan EG (EPA Reg. No. 7969-85); and Curalan (EPA Reg. No. 7969-62). Vinclozolin is used on many types of ornamentals to control a variety pests throughout the growing season as noted above. Applications are made either as a preventative or as a curative to control ongoing pest problems. The maximum single event application rate could not be established as the labels are inconclusive (even after several inquiries to BASF). The labels indicate to "repeat every 10 to 14 days as needed." Application equipment includes thermal foggers. The labels also indicated that "in a separate container prepare fogging solution of 19 fluid ounces of VK-11 carrier solution and 51 ounces of water. Then add the appropriate amount of Curalan." The maximum seasonal application rate is 8 lb ai per acre. No information was provided in the recent QUA (11/99) that provided information on typical application rates (i.e., including both single application events and on a seasonal basis).

C **Post-harvest cut flower (Dip):** This summary is based on the revised QUA (Quantitative Usage Analysis) of 11/3/99 and the following labels: Curalan DF (EPA Reg. No. 7969-85); Curalan EG (EPA Reg. No. 7969-85); and Curalan (EPA Reg. No. 7969-62). Applications are made as a preventative to control gray mold (*botrytis gladiorum*) on gladiolus and/or *botrytis cinerea* on cut roses in cold storage or transit. The available labels indicate "as a post-harvest dip, dip flower buds 3 to 4 seconds in a solution of 1.5 to 3 pounds per 100 gallons of water" (i.e., a solution concentration of up to 0.015 lb ai/gallon). Applications are to be made "after grading and prior to cold storage." Application equipment was not specified on the label. The Agency believes that on open vat type of dip tank is used in conjunction with hand-dipping procedures. The maximum single application rate is equivalent to the seasonal application rate as cut flowers are only dipped once prior to transit and storage. No information was provided in the recent QUA (11/99) that provided information on typical application rates or details on the method of application.

C **Post-harvest cut flower (Foliar Spray):** This summary is based on the revised QUA (Quantitative Usage Analysis) of 11/3/99 and the following labels:Curalan DF (EPA Reg. No. 7969-85); Curalan EG (EPA Reg. No. 7969-85); and Curalan (EPA Reg. No. 7969-62). Applications are made as a preventative to control gray mold (*botrytis gladiorum*) on gladiolus and/or *botrytis cinerea* on cut roses in cold storage or transit. The available labels indicate that cut flowers are to be treated using a solution at a concentration of "1.5 to 3 pounds [end-use product] per 100 gallons of water" (i.e., a solution concentration of up to 0.015 lb ai/gallon). Applications are to be made "after grading and prior to cold storage." Application equipment was not specified on the label. However, the Agency believes that common handheld equipment such as low pressure handwands and backpack sprayers are used. The maximum single application rate is equivalent to the seasonal application rate as cut flowers are only treated once prior to transit and storage. No information was provided in the recent QUA (11/99) that provided information on typical application rates or specific details on the method of application.

C **Bulbs and corm (Dip):** This summary is based on the revised QUA (Quantitative Usage Analysis) of 11/3/99 and the following labels: Curalan DF (EPA Reg. No. 7969-85); Curalan EG (EPA Reg. No. 7969-85); and Curalan (EPA Reg. No. 7969-62). Applications are made as a preventative to control gray mold (*botrytis gladiorum*) after harvest but prior to storage. The available labels indicate applications are to be made by dipping in a solution prepared by adding from 1 to 2 pounds per 100 gallons of water" (i.e., a solution concentration of up to 0.01 lb ai/gallon). Application equipment was not specified on the label. The Agency believes that an open vat type of dip tank is used in conjunction with hand-dipping procedures. The maximum single application rate is equivalent to the seasonal application rate as bulbs and corm are only dipped once prior to storage after harvest. No information was provided in the recent QUA (11/99) that provided information on typical application rates or details on the method of application.

- **Budwood and barefoot nursery stock:** This summary is based on the revised QUA (Quantitative Usage Analysis) of 11/3/99 and the following labels: Curalan DF (EPA Reg. No. 7969-85); Curalan EG (EPA Reg. No. 7969-85); and Curalan (EPA Reg. No. 7969-62). Applications are made as a preventative to control gray mold (*botrytis gladiorum*) after harvest but prior to storage. The available labels indicate applications are to be made by dipping in a solution prepared by adding 1.5 pounds per 100 gallons of water" (i.e., a solution concentration of 0.0075 lb ai/gallon). Application equipment was not specified on the label. The Agency believes that on open vat type of dip tank is used in conjunction with hand-dipping procedures. The maximum single application rate is equivalent to the seasonal application rate as bulbs and corm are only dipped once prior to storage after harvest. No information was provided in the recent QUA (11/99) that provided information on typical application rates or details on the method of application.

- **Turfgrass:** This summary is based on the revised QUA (Quantitative Usage Analysis) of 11/3/99 and the following labels: Curalan DF (EPA Reg. No. 7969-85); Curalan EG (EPA Reg. No. 7969-85); and Curalan (EPA Reg. No. 7969-62). Vinclozolin is used on turf to control a variety pests throughout the growing season as noted above. Applications are made either as a preventative or as a curative to control ongoing pest problems. Generally, the curative rates are approximately 2 times the corresponding rate for preventative applications. The maximum single event application rate is 1.35 ai/acre (i.e., 0.031 lb ai/1000 ft^2). All BASF labels, 7969-XX, have a maximum application rate of 1.35 lb ai/acre based on information contained in two 1998 letters to the Agency (A. Tobia of BASF to L. Rossi and J. Jones of EPA). Applications are to be made in volumes of water ranging from 40 to 160 gallons per acre (i.e., 1 to 4 gallons per 1000 ft^2). The labels indicate that the interval between applications can range from 10 to 28 days depending upon the pests being controlled. The labels also instruct users to "re-treat at shorter intervals or use higher rates if conditions favorable to disease exist." Application equipment includes groundboom, and a variety of handheld methods including low pressure handwands, high pressure handwands, backpack sprayers, and low-pressure/high-volume turfguns. The maximum seasonal application rate is 4 lb ai per acre. No information was provided in the recent QUA (11/99) that provided information on typical application rates (i.e., including both single application events and on a seasonal basis).

b. Occupational and Residential Exposure/Risk Assessment

The Agency has determined that there is a potential for exposure in both occupational and residential scenarios from the occupational handling of vinclozolin products during the application process and/or from entering areas previously treated with vinclozolin. As a result, risk assessments have been completed for both occupational handler and postapplication scenarios as well as residential postapplication scenarios. The exposure and risk assessments that have been completed are described in this section. All risks assessments are structured based on the toxicity of the chemical being considered. The toxicological endpoints that have been selected for vinclozolin are included in *Section 2.b.i: Toxicity Endpoints Used in the Exposure/Risk Assessment*. This assessment considers exposures to individuals during the application process (referred to as handlers) and also after application. A description of both the occupational handler exposure scenarios that serve as the basis for this assessment are presented in *Section 2.b.ii: Handler Exposure Scenarios*. The mechanics of how the handler risk assessment was completed and the data used in that assessment are presented in *Section 2.b.iii: Handler Exposure and Risk Assessment*. A description of both the occupational and residential postapplication exposure scenarios that serve as the basis for this assessment are presented in *Section 2.b.iv: Post-Application Exposure Scenarios*. The mechanics of how the postapplication risk assessment was completed and the data used in that assessment are presented in *Section 2.b.v: Post-Application Exposure and Risk Assessment*.

i. Toxicity Endpoints Used in the Exposure/Risk Assessment

A series of toxicological endpoints were used to complete the handler and post-application risk assessments. The endpoints that were used to complete this assessment are summarized below (by applicable route and duration) in order to provide a quick reference to the occupational and residential risk assessments.

- **Short- and Intermediate-Term Dermal (For Females 13+ Years):** NOAEL of 3 mg/kg/day based on statistically significant decreases in male prostate weights from a pre-natal developmental toxicity study in rats (Gray 1996, MRIDs 44395701 and 44395702);

- **Short- and Intermediate-Term Dermal (For Infants and Children):** NOAEL of 5 mg/kg/day based on statistically significant decreases in preputial separation (a measure of puberty) from a post-natal developmental toxicity study in rats (Gray at October 1996 meeting of the FIFRA SAP);

- **Long-Term (Chronic) Dermal (For General Population):** NOAEL of 1.2 mg/kg/day based on foam cell aggregates in the lungs (males), eosinophilic foci in the liver (males), interstitial cell lipidosis in the ovaries (females) and lenticular degeneration of the eyes (both sexes) from a chronic toxicity study in rats (MRIDs 43254701, 43254702, 43254703);

- **Dermal Absorption:** 25.2 percent based on a rat dermal absorption study (MRID 41824309);

- **Short- and Intermediate-Term Inhalation (For Females 13+ Years):** NOAEL of 3 mg/kg/day based on statistically significant decreases in male prostate weights from a pre-natal developmental toxicity study in rats (Gray 1996, MRIDs 44395701 and 44395702);

- **Short- and Intermediate-Term Inhalation (For Infants and Children):** NOAEL of 5 mg/kg/day based on statistically significant decreases in preputial separation (a measure of puberty) from a developmental toxicity study in rats (Gray at 10/96 FIFRA SAP meeting);

- **Long-Term (Chronic) Inhalation (For General Population):** NOAEL of 1.2 mg/kg/day based on foam cell aggregates in the lungs (males), eosinophilic foci in the liver (males), interstitial cell lipidosis in the ovaries (females) and lenticular degeneration of the eyes (both sexes) (MRIDs 43254701, 43254702, 43254703);

- **Inhalation Absorption:** 100 percent with route-to-route extrapolation is required;

- **Short- and Intermediate-Term Non-dietary Ingestion:** no endpoint was selected by the HIARC for infants and toddlers for acute dietary exposures (the population that would be considered in this type of assessment), therefore, the oral administration endpoint of 5 mg/kg/day from a rat developmental study has been used to address non-dietary exposures;

- **Chronic Duration Non-dietary Ingestion:** these types of exposures are not expected to occur given the use pattern for vinclozolin;

- **Uncertainty Factors Applied to Non-cancer Occupational Assessments:** 100 for both short-term/intermediate-term scenarios with exposure durations;

- **Uncertainty Factors Applied to Non-cancer Residential Assessments:** 1000 for both short-term/intermediate-term scenarios with exposure durations, this overall factor includes application of the FQPA 10x factor for increased susceptibility in children;

- **Cancer Using Linear Low-Dose Extrapolation:** Q_1* of 2.9 x 10^{-1} $(mg/kg/day)^{-1}$ for quantification of human health risk is based on moderate interstitial call tumor rates in male rats and applied to only longer-term exposures based on available cancer mechanism data;

- **Cancer Using Threshold (MOE) Approach:** 4.9 mg/kg/day for quantification of human risk, applied to only longer-term exposures based on available cancer mechanism data; and

- **Uncertainty Factors Applied to Cancer Assessments:** not defined given the ongoing scientific debate over appropriate values -- cancer MOE values were calculated and presented in conjunction with corresponding risk values calculated using the Q_1* for characterization purposes.

ii. Handler Exposure Scenarios

Exposure scenarios can be thought of as ways of categorizing the kinds of exposures that occur related to the use of a chemical. The use of scenarios as a basis for exposure assessment is very common as described in the *U.S. EPA Guidelines For Exposure Assessment* (U.S. EPA; Federal Register Volume 57, Number 104; May 29, 1992). The purpose of this section is to describe the exposure scenarios that were used by the Agency in the assessment for vinclozolin handlers and to explain how the scenarios were defined. Information from the current labels; use and usage information; toxicology data; and exposure data were all key components in the developing the exposure scenarios.

The Agency uses the term "Handlers" to describe those individuals who are involved in the pesticide application process. The agency believes that there are distinct job functions or tasks related to applications and that exposures can vary depending on the specifics of each task. Job requirements (e.g., amount of chemical to be used in an application), the kinds of equipment used, the crop or target being treated, and the circumstances of the user (e.g., the level of personal protection used by an applicator) can cause exposure levels to differ in a manner specific to each scenario.

The Agency uses a concept known as *unit exposure* as the basis for the scenarios used to assess handler exposures to pesticides. *Unit exposures* numerically represent the exposures one would receive related to an application, they are generally presented as (mg active ingredient exposure/pounds of active ingredient handled). The Agency has developed a series of unit exposures that are unique for each scenario typically considered in our assessments (i.e., there are different unit exposures for different types of application equipment; job functions; and levels of protection). The *unit exposure* concept has been established in the scientific literature and also through various exposure monitoring guidelines published by the U.S. EPA and international organizations such as Health Canada and OECD (Organization For Economic Cooperation and Development). The concept of unit exposures can be illustrated by the following example. If an individual makes an application using a groundboom sprayer with either 10 pounds of chemical A or 10 pounds of chemical B using the same application equipment and protective measures, the exposures to chemicals A and B would be similar. The unit exposure in both cases would be 1/10th of the total exposure (measured in milligrams) received during the application of either chemical A or chemical B (i.e., milligrams on the skin after applying 10 pounds of active ingredient divided by 10 pounds of active ingredient applied).

The first step in the handler risk assessment process is to identify the kinds of individuals that are likely to be exposed to vinclozolin during the application process. In order to do this in a consistent manner, the Agency has developed a series of general descriptions for tasks that are associated with pesticide applications. Common tasks (as an example) can include: preparation of dilute, water-based spray solutions for application; transferring or loading dilute spray solutions into sprayers for application; and making applications with specific types of equipment such as a groundboom or airblast sprayer. The Agency also considers whether or not individuals use pesticides as part of their employment (referred to as occupational risk assessments) or if they are individuals who purchase and use pesticide products in and around their residences (referred to as homeowners, there are no products containing vinclozolin that are currently offered for sale to homeowners). Tasks associated with pesticide use (i.e., for "handlers") can generally be categorized using one of the following terms:

- **Occupational Mixer/loaders:** these individuals perform tasks in preparation for an application. For example, they would prepare dilute spray solutions and/or load/transfer solid materials (e.g., granulars) or dilute spray solutions into application equipment such as a groundboom tractor or planter prior to application.

- **Occupational Applicators:** these individuals operate application equipment during the release of a pesticide product into the environment. These individuals can make applications using equipment such as groundboom sprayers or tractor-drawn spreaders for granular materials.

- **Occupational Mixer/loader/applicators:** these individuals are involved in the entire pesticide application process (i.e., they do all job functions related to a pesticide application event). These individuals would prepare a dilute spray solution and then also apply the solution. The Agency always considers some exposures to be mixer/loader/applicator exposures because of the equipment used and the logistics associated with such applications. For example, if one uses a small handheld device such as a 1 gallon low pressure handwand sprayer it is anticipated that one individual will mix a spray solution and then apply the solution because of labor and logistical considerations.

C **Occupational Flaggers:** these individuals guide aerial applicators during the release of a pesticide product onto an intended target.

There are individuals who use vinclozolin that fit into each of the job function categories described above. Therefore, the vinclozolin risk assessment for handlers contains exposure scenarios in each category.

The next step in the risk assessment process is to define what kinds of equipment, packaging, and formulation types (as well as other kinds of factors that can vary in specific assessments) can be used by individuals when making vinclozolin applications. In agriculture, vinclozolin can be used occupationally to treat fruits such as kiwi and raspberries and also field crops such as canola, lettuce, onions, and snapbeans. Most applications of vinclozolin in agriculture involve dry flowables or extruded granules that are diluted in water and applied as a spray. There are also wettable powders and flowable liquid concentrates that are also diluted and applied as a spray. Vinclozolin labels do not specify all particular types of application equipment for these crops as is common for most pesticide labels. Therefore, in order to complete exposure assessments for handlers, the Agency must evaluate what crops and other targets can be treated and then determine what application methods are likely to be used to make an application. It is expected that vinclozolin applications are routinely made with equipment that is common in agriculture including groundboom sprayers, airblast sprayers, and fixed-wing aircraft (also representing helicopters for the purposes of this assessment). The use of chemigation (i.e., irrigation) equipment is prohibited on some labels. Vinclozolin can be also be occupationally applied in agriculture to chicory/endive prior to storage and/or while forcing plants. The applications are completed using a dry flowable formulation which is diluted in water and either sprayed (likely with low pressure handwands or backpack sprayers) before cold storage or treated by adding vinclozolin to the propogation trays.

Vinclozolin can also be occupationally applied to ornamentals including established woody and herbaceous plants and flowers, some types of cut flowers, bulbs and corm, budwood and barefoot nursery stock, and turf. Applications are expected to be completed within greenhouses and also outdoors to established ornamentals or during propogation activities (e.g., to large shrubs including azaleas and rhododendron). Most applications of vinclozolin to ornamentals involve dry flowables or extruded granules that are diluted in water and applied as a spray, used as a plant/flower dip, or used to fog greenhouses with thermal fogging equipment. There are also wettable powders and flowable liquid concentrates that are diluted and applied as the other formulations. Vinclozolin labels do not specify all particular types of application equipment as is common for most pesticide labels. Therefore, in order to complete exposure assessments for handlers, the Agency must evaluate what crops and other targets can be treated and then determine what application methods are likely to be used to make an application. A suite of application methods are selected for risk assessment purposes by the Agency when uses on ornamentals are identified because many types of application equipment are available and no application method is specified or precluded on the current labels. Therefore, handlers can use their own discretion to select and use any functional method to make an application. To ensure that the potential risks associated with the use of vinclozolin are addressed it is necessary to evaluate all potential application methods in the assessment. The suite of application methods selected by the Agency for this risk assessment includes handheld equipment that is common in the ornamental and floriculture industries such as high pressure handwands, low pressure/high volume turfguns, backpack sprayers, and low pressure handwands. Many types of ornamentals can also be treated by dipping processes. For example, cut flowers (e.g., roses) are dipped as a preventative measure during cold storage and shipment. Bulbs and corm as well as barefoot nursery stock can also be dipped. Finally, turfgrass can also be treated using groundboom equipment in some circumstances such as on sod farms.

There are no products intended for sale to homeowners. As such, the Agency did not include any homeowner handler exposure scenarios in this assessment.

Next, assessors must understand how exposures to vinclozolin occur (i.e., frequency and duration) and how these patterns can cause the toxicological effects of the chemical to differ (referred to as dose response). Wherever possible, use and usage data determine the appropriateness of certain types of risk assessments (e.g., a chronic risk assessment is not warranted for vinclozolin in most circumstances because chronic duration exposure patterns generally do not occur). Other parameters are also defined from use and usage data such as application rates and application frequency. The Agency always completes risk assessments using maximum application rates for each scenario because what is possible under the label (the legal means of controlling pesticide use) must be evaluated, for complete stewardship, in order to ensure there are no concerns for each specific labeled use. Additionally, whenever the Agency has additional information such as typical application rates for some crops/uses, as in this case, it uses the information to further evaluate the overall risks associated with the use of the chemical in order to allow for a more informed risk management decision. In this case, average application rates (considered to be the same as typical rates for the purposes of this assessment) defined in the recent *Quantitative Usage Analysis* were available for some crops and integrated into the assessment.

A chemical can produce different effects based on the duration of exposure, the frequency of exposure, and the level of exposure. It is likely that vinclozolin exposures can occur in a variety of patterns. The Agency believes that occupational vinclozolin exposures can occur over a single day or up to weeks at a time even though each crop or application target is generally treated only once or twice per season according to the recent QUA (i.e., labels allow more frequent applications). Intermittent exposures over several weeks are also anticipated. Some applicators may apply vinclozolin over a period of weeks because they need to cover large acreages, they may be custom or professional applicators that are completing a number of applications within a region, or they may be applying vinclozolin over a period of several days (e.g., a greenhouse worker who dips barefoot nursery stock periodically over a period of several weeks). The Agency classifies exposures of one week or less as short-term exposures and exposures of 1 week to several months (i.e., up to 6 months) as intermediate-term exposures. The Agency completes both short- and intermediate-term assessments for occupational scenarios in essentially all cases because these kinds of exposures are likely and acceptable use and usage data are not available to justify deleting intermediate-term assessments. In certain cases, the Agency also believes that chronic exposures (i.e., at least 180 days per year) can occur due to the use (foliar spray) of vinclozolin on herbaceous ornamentals and cut flowers in propagation greenhouses and also from dipping ornamentals such as cut flowers in propagation facilities. For vinclozolin, the agency has selected two sets of toxicological endpoints to address short- and intermediate-term exposure durations together as well as chronic exposures. The endpoint selected for short- and intermediate-term exposures is based on decreased prostate weight in male fetuses as observed in a prenatal rat developmental study. Another endpoint applicable to exposures that have chronic durations (i.e., exceeding 180 days) was selected as the duration of the effect observed in the developmental study is not appropriate for comparison with this duration of exposure. The endpoint used to calculate risks for chronic exposures where extended periods of exposures are expected to occur for a small number of exposure scenarios (e.g., dipping or treating cut flowers), was selected from a chronic feeding study in rats in which several effects were noted including foam cell aggregates in the lungs (males), eosinophilic foci in the liver (males), interstitial cell lipidosis in the ovaries (females), and lenticular degeneration of the eyes (both sexes). As a result, two non-cancer risk assessments have been completed for the occupational handler exposures to vinclozolin including for short-term/intermediate-term durations up to 180 days and for chronic durations greater than 180 days (where applicable). The Agency has also completed a cancer risk assessment for a small number of exposure scenarios where extended periods of exposures are thought to occur using both a threshold mechanism (cancer MOE) and linear low dose extrapolation (Q_1*) approach. This assessment was completed because available biological mechanism data indicate that cancers occur only after extended periods of exposure. For the cancer assessment, the frequency of exposure (number of events per year) is noted below in section 2.b.iii for each scenario considered. To summarize, the Agency has completed four types of risk assessments for vinclozolin based on the duration of exposure and the mechanism of toxicity (i.e., 2 for noncancer and 2 cancer assessments).

The toxicity of chemicals can also vary based on the route of exposure or how a chemical enters the body. For example, dermal exposures can result in a different toxic effect and/or severity of reaction than inhalation exposures. The toxicology database for vinclozolin, however, is based on oral administration studies (i.e., a single study was selected for both routes for each duration considered) indicating that the Agency needed to consider total risks by simultaneously calculating exposures to the skin in conjunction with exposures via inhalation. This approach for calculating total exposures and risks for vinclozolin has been applied to all durations of exposure since the corresponding endpoints used to calculate risks from dermal exposure and from inhalation exposures are the same for each duration of exposure and toxic effect identified (including cancer). The endpoints selected and how they are applied in the risk assessment has been presented above in *Section 2.b.i: Toxicity Endpoints Used in the Exposure/Risk Assessment*.

Occupational handler exposure assessments are completed by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (or cancer risk) or until all options are exhausted (i.e., going from minimal to maximum levels of protection). The lowest tier is represented by the baseline exposure scenario followed by increasing the levels of personal protection represented by personal protective equipment or PPE (e.g., gloves, extra clothing, and respirators) and engineering controls (e.g., closed cabs and closed loading systems). This approach is always used by the Agency in order to be able to define label language using a risk-based approach and not based on generic requirements for label language. In addition, the minimal level of adequate protection for a chemical is generally considered by the Agency to be the most practical option for risk reduction (i.e., over-burdensome risk mitigation measures are not generally considered a practical alternative or solution for regulatory action). For vinclozolin, four distinct levels of dermal protection were considered in the assessment to account for the use of standard work clothing (long-pants and long-sleeved shirt), standard work clothing with a pair of gloves, standard work clothing with a pair of chemical-resistant gloves and an additional layer of clothing such as coveralls, and the use of engineering controls. Additionally, four levels of respiratory protection were considered in the assessment to account for no respiratory protection, the use of dust/mist PF 5 or PF 10 air purifying respirators (PF = protection factor), and the use of engineering controls. [Note: The manner in which these calculations have been completed allow for flexibility in determining final protective measures -- see Section 2.c for further details.] In summary, the levels of protection that formed the basis for the calculations in this assessment include (note that the results can be mixed as matched as described in Section 2.c):

- **Baseline:** Represents typical work clothing or a long-sleeved shirt and long pants with no respiratory protection. No chemical-resistant gloves are included in this scenario.

- **Minimum Personal Protective Equipment (PPE):** Represents the baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5.

- **Maximum Personal Protective Equipment (PPE):** Represents the baseline scenario with the use of an additional layer of clothing (e.g., a pair of coveralls), chemical-resistant gloves, and an air purifying respirator with a protection factor of 10.

- **Engineering Controls:** Represents the use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods since there are no known devices that can be used to routinely lower the exposures for these methods.

Given all of the information above, the scenarios that have been developed for each specific occupational use of vinclozolin include (the scenario numbers correspond to the tables of risk calculations included in the occupational risk calculation aspects of the appendices):

<u>For Occupational Treatments on Ornamental Use Sites (*+):</u>

(1a) mixing/loading dry flowables for aerial and chemigation applications;
(1b) mixing/loading dry flowables for airblast applications;
(1c) mixing/loading dry flowables for groundboom applications;
(1d) mixing/loading dry flowables for high-pressure handwand applications;
(1e) mixing/loading dry flowables for dipping applications;
(1f) mixing/loading dry flowables for thermal fogging applications;
(1g) mixing/loading dry flowables for low pressure/high volume turfgun applications;
(2a) mixing/loading liquid flowables for aerial applications;
(2b) mixing/loading liquid flowables for airblast applications;
(2c) mixing/loading liquid flowables for groundboom applications;
(2d) mixing/loading liquid flowables for high-pressure handwand applications;
(2e) mixing/loading liquid flowables for dipping applications;
(2f) mixing/loading liquid flowables for thermal fogging applications;
(2g) mixing/loading liquid flowables for low pressure/high volume turfgun applications;
(3a) mixing/loading extruded granules for aerial and chemigation applications;
(3b) mixing/loading extruded granules for airblast applications;
(3c) mixing/loading extruded granules for groundboom applications;
(3d) mixing/loading extruded granules for high-pressure handwand applications;

(3e) mixing/loading extruded granules for dipping applications;
(3f) mixing/loading extruded granules for thermal fogging applications;
(3g) mixing/loading extruded granules for low pressure/high volume turfgun applications;
(4) applying sprays with an airblast sprayer;
(5) applying sprays with a groundboom sprayer;
(6) applying sprays with a fixed-wing aircraft (also accounts for helicopter applications);
(7) application by thermal fogging in greenhouses;
(8) applying by dipping cut flowers, nurserystock, or bulbs and corm;
(10) applying using a high-pressure handwand sprayer;
(11) applying using a low-pressure/high-volume turfgun sprayer;
(12) mixing/loading/applying using a low-pressure handwand sprayer;
(13) mixing/loading/applying using a backpack sprayer; and
(14) flagging for aerial spray application.

<u>For Occupational Uses In Agriculture on Terrestrial Crops/Targets (*+):</u>
(1a) mixing/loading dry flowables for aerial and chemigation applications;
(1b) mixing/loading dry flowables for airblast applications;
(1c) mixing/loading dry flowables for groundboom applications;
(1d) mixing/loading dry flowables for greenhouse forcing tray applications;
(2a) mixing/loading liquid flowables for aerial applications;
(2b) mixing/loading liquid flowables for airblast applications;
(2c) mixing/loading liquid flowables for groundboom applications;
(3a) mixing/loading extruded granules for aerial and chemigation applications;
(3b) mixing/loading extruded granules for airblast applications;
(3c) mixing/loading extruded granules for groundboom applications;
(4) applying sprays with an airblast sprayer;
(5) applying sprays with a groundboom sprayer;
(6) applying sprays with a fixed-wing aircraft (also accounts for helicopter applications);
(9) applying to chicory/endive rootstock in forcing tray;
(12) mixing/loading/applying using a low-pressure handwand sprayer;
(13) mixing/loading/applying using a backpack sprayer; and
(14) flagging for aerial spray application.

* assessed at each appropriate level of personal protection described above
\+ assessed at typical (if available) and maximum application rates

iii. Handler Exposure and Risk Assessment

The Agency considers how chemical exposures occur (the frequency and duration) and also how chemicals enter the body (because the toxic effects can be different), as described in Section 2.b.ii above, when developing risk assessments. There are a variety of toxicological concerns over vinclozolin ranging from developmental effects for short- and intermediate-term exposures through concerns over cancer. To evaluate all of these types of risk concerns, the Agency has completed four distinct risk assessments for vinclozolin handlers including:

- Short- and Intermediate-Term Duration (<180 days);
- Chronic (Long-term) Duration (>180 days);
- Cancer Risk Assessment Using Threshold Mechanism Approach; and
- Cancer Risk Assessment Using Linear, Low Dose Extrapolation Approach.

Calculations:

Exposure levels are calculated in a manner that accounts for the method of application, the level of personal protection used during application, and the amount of chemical handled in an application (i.e., proportional to application rate and the amount treated per day). Both daily dermal and daily inhalation exposures have been calculated for each type of assessment completed. In all cases, risks were calculated individually for each route of exposure then added to calculate total body burden (represented by total absorbed dose).

In all cases, daily dermal exposure levels were calculated. Daily dermal exposure is generally calculated using the following formula:

Daily Dermal Exposure (mg ai/day) =

Unit Exposure (mg ai/lb ai) x Application Rate (lb ai/A) x Daily Acres Treated (A/day)

Where:

Daily Dermal Exposure = Amount deposited on the surface of the skin that is available for dermal absorption, also referred to as potential dose (mg ai/day);
Unit Exposure = Normalized exposure value derived from May 1997 PHED Surrogate Exposure Table and chemical-specific handler data available for this assessment (mg ai/pound ai applied);
Application Rate = Normalized application rate based on a logical treatment unit such as acres or on a per unit treated basis, a maximum value is generally used (lb ai/A); and
Daily Acres Treated = Normalized application area based on a logical unit treatment such as acres or numbers of animals (A/day or animals/day).

The next step was to calculate the daily inhalation exposures for handlers. The process used was similar to that used to calculate the daily dermal dose to handlers. Daily inhalation exposure levels were are presented as (µg/lb ai) values in the *PHED Surrogate Exposure Table* of May 1997 or the December 1997 *SOPs for Residential Exposure Assessment Surrogate Exposure Table* for homeowner applications (i.e., these values are based on an inhalation rate of 29 liters/minute and an 8 hour exposure interval). Once the unit exposure value is presented in this form and converted to (mg/lb ai), the calculations essentially mirror those presented above for the dermal route using a value of 100 percent absorption (i.e., a daily inhalation dose is calculated in mg/kg/day).

also do not include any dose attributable to nondietary ingestion (e.g., hand-to-mouth activity).

Daily dose (i.e., a biologically appropriate and available dose resulting from dermal exposure) was then calculated by normalizing the daily exposure value by body weight and accounting for absorption. For adult handlers using vinclozolin, a body weight of 60 kg was used for all noncancer exposure scenarios because the toxic effect (decreased prostate weights in male offspring) is from a prenatal developmental toxicity study (i.e., it is sex-specific). For the cancer calculations, a body weight of 70 kg was used as this value reflects the general population (i.e., it is not sex-specific). Additionally, dermal absorption factor of 25.2 percent and an inhalation absorption factor of 100 percent were used for all calculations. Daily dose was calculated using the following formula:

$$Daily\ Dose\left(\frac{mg\ ai}{kg/day}\right) = Daily\ Exposure\left(\frac{mg\ ai}{day}\right) x \left(\frac{AbsorptionFactor(\%/100)}{Body\ Weight\ (kg)}\right)$$

Where:

Daily Dose = the amount as absorbed dose, from dermal or inhalation exposures, received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day);
Daily Exposure = the amount of dermal (on the skin) or inhalation (inhaled) exposure calculated above (mg pesticide active ingredient/day);
Absorption Factor = a measure of the flux or amount of chemical that crosses a biological boundary (% of the total available); and
Body Weight = body weight determined to represent the population of interest in a risk assessment (kg).

[Note: The U.S. EPA Exposure Assessment Guidelines (EPA, 1992) define potential dose as the amount of a chemical at the absorption barrier. Additionally, absorbed dose is defined as the amount of a chemical that has been absorbed and is available for interaction with biologically significant receptors.]

Risks in this assessment were calculated using two different approaches based on the toxicological effect being evaluated. Risks attributable to noncancer effects were calculated in a non-probabilistic manner using the Margin of Exposure (MOE) which is a ratio of the calculated exposure to the appropriate toxic endpoint of concern. For most exposures (which are anticipated to be less than 6 months) MOEs were calculated by comparing exposures to the endpoint defined from a prenatal developmental toxicity study in rats (i.e., decreased prostate weights with a NOAEL of 3 mg/kg/day). This endpoint was used to calculate MOE values attributable to dermal exposure and also to inhalation exposure. For exposures longer than 180 days, MOEs were calculated by using an endpoint from a chronic rat toxicity study (i.e., several effects noted with a NOAEL of 1.2 mg/kg/day). [Note: See Section 2.b.i for more details about the specific endpoints used in each assessment.] MOEs were calculated using the formula below:

$$MOE = \frac{Endpoint\ (NOAEL)\left(\frac{mg}{kg/day}\right)}{Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

Where:

Where:

MOE = margin of exposure or value used by the Agency to represent noncancer risk or how close a chemical exposure is to being a concern (unitless);
Daily Dose = the absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day); and
Endpoint (LOAEL, NOAEL) = dose level in a toxicity study where no observed adverse effects occurred in the study (mg pesticide active ingredient/kg body weight/day).

MOEs were added together in order to consider total risks to handler given that the noncancer toxic effect for each route of exposure (e.g., to the skin and being inhaled) is the same. The equation the Agency uses to add MOEs together is presented below:

$$MOE_{total} = 1/((1/MOE_a) + (1/MOE_b) +.... (1/MOE_n))$$

Where:

MOE_a, MOE_b, and MOE_n represent MOEs for each exposure route of concern

A margin of exposure (MOE) uncertainty factor of 100 is considered an appropriate risk level for all occupational exposures to vinclozolin regardless of the duration. This factor was determined based on the standard Agency approach of accounting for inter-species variability and intra-species sensitivity.

In addition to the noncancer assessments that have been completed for vinclozolin, the Agency also has concerns over the development of cancer from exposure to vinclozolin. Two types of these calculations were completed. The first type was based on a threshold approach using MOEs as the measure of cancer risk. The cancer MOEs were calculated as described above for the noncancer effects with the appropriate toxicological endpoint. The other type of cancer risk calculation using the linear low-dose extrapolation first requires the calculation of a LADD (Lifetime Average Daily Dose) using the following equation:

$$LADD_{abs} = Daily\ Dose_{abs} * (Frequency/365) * (Exposure\ Duration/Lifetime\ Duration)$$

Where:

$LADD_{abs}$ = Internal or absorbed daily dose amortized over an individual's lifetime (mg pesticide active ingredient/kg body weight/day);
Daily $Dose_{abs}$ = the amount of absorbed dose received from exposure to a pesticide in a given scenario, as calculated above for MOE analysis -- only internal or absorbed dose is appropriate for cancer calculations (mg pesticide active ingredient/kg body weight/day);
Frequency = the number of days exposed to a pesticide of concern per annum (days/year);
Exposure Duration = the number of years throughout a lifetime that a person is exposed to a specific chemical (years); and
Lifetime = anticipated lifetime of an individual in the exposure population of interest (years).

[Note: The U.S. EPA Exposure Assessment Guidelines (EPA, 1992) define absorbed dose as the amount of a chemical that has been absorbed and is available for interaction with biologically significant receptors.]

Once LADD values were calculated for each scenario of concern, cancer risks were calculated using the Q_1* value for vinclozolin of 2.9 x 10^{-1} (mg/kg/day)$^{-1}$. Generally, the use of a Q_1* approach is based on the premise that there is no dose threshold in the carcinogenic mechanism and any dose received can be related to a cancer risk in a linear fashion (i.e., referred to as linear low dose extrapolation). However, the available cancer mechanism data for vinclozolin indicate that linear extrapolation of dose is only applicable after extended periods of exposure. Therefore, the Agency has completed a cancer risk assessment only for exposures that meet this criteria. Cancer risks represent a the probability of excess cancer cases in a population over a lifetime. Cancer risks have been calculated by the Agency using the following equation:

$$\text{Risk} = \text{LADD}_{\text{int}} * (Q_1*)$$

Where:

Risk = the probability of deleterious health effects as described in the U.S. EPA Exposure Assessment Guidelines of May 1992 (unitless);
LADD $_{abs}$ = Internal daily dose amortized over an individual's lifetime as calculated above (mg pesticide active ingredient/kg body weight/day); and
Q_1* = measure of cancer potency (mg/kg/day)$^{-1}$.

<u>Handler Risk Assessment Results:</u>

All occupational handler exposure and risk calculations are presented in the tables contained in *Appendix A: Occupational Handler Exposure and Risk Assessment For Vinclozolin.* Table 1 contains information that can be used to describe the exposure data used in the analysis. The origin of each unit exposure value is presented along with information pertaining to the quality of the data used to calculate each value. The assessment of data quality is based on the number of observations and the available quality control data. The quality control data are assessed based on Agency guidelines and a grading criteria established by the Pesticide Handlers Exposure Database task force. Other exposure factors (i.e., descriptions of each scenario, application rates, and acres treated), unit exposure values at varying levels of mitigation (such as personal protection), and toxicological parameters used in the noncancer risk assessments are presented in Table 2. The calculation of baseline exposures (mg/day), dose levels, and the resulting Margins of Exposure (MOEs) for cancer and noncancer effects are presented in Table 3. Tables 4, 5, and 6 contain similar calculations for increased levels of personal protection. Noncancer MOE values calculated for the use of additional mitigation in the form of minimum personal protective equipment are presented in Table 4 (single layer clothing with gloves and a PF 5 respirator) while values calculated for the use of additional mitigation in the form of maximum personal protective equipment (double layer clothing with gloves and a PF 10 respirator) are presented in Table 5. Table 6 contains noncancer MOE values that reflect the use of appropriate engineering controls. Tables 7 through 11 in Appendix A present summary results of the noncancer risk assessment that are also discussed in more detail in the section 2.c of this document. Table 12 contains the calculated absorbed daily dose levels (ADDs) that are required to complete the cancer risk assessment. Tables 13 and 14 contain the LADDs (Lifetime Average Daily Dose levels) and resulting cancer risks calculated using linear low-dose extrapolation for handlers at a lower application frequency (i.e., 90 days per year). Likewise, Tables 15 and 16 contain the LADDs (Lifetime Average Daily Dose levels) and resulting cancer risks calculated using linear low-dose extrapolation for handlers at a higher application frequency (i.e., 180 days per year).

Exposure Data and Factors:

The data and factors described in the exposure calculations above are discussed in more detail below. These factors include: unit exposures; application rate; acres treated per day; and frequency of application as well as any other factors that should be considered in the calculation of exposure.

Chemical-specific exposure monitoring data for assessing human exposures during pesticide handling activities were submitted to the Agency in support of the reregistration of vinclozolin. It is the policy of the Agency to combine submitted chemical-specific data with those from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions because individual studies may not encompass the variety of agricultural equipment in use throughout the country and also due to the inter-variability of exposures among handlers (U.S. EPA, 1986). The studies that were submitted include two handler exposure monitoring studies and a supporting freezer storage stability study that were developed using passive dosimetry monitoring techniques (both also have a biological monitoring component which is considered indeterminant from a quantitative perspective and not quantitatively used in this risk assessment). The passive dosimetry components of these studies are actually included in the currently available version of PHED (V 1.1) as BASF has previously waived them into the system. Therefore, separate calculations were not completed using the chemical-specific passive dosimetry data as, per Agency policy, the data from these studies is already reflected in the current unit exposure values used by the Agency. The passive dosimetry results from these two studies are also qualitatively supported by the available biological monitoring data. A vinclozolin-specific epidemiology study has also been completed that evaluated factory worker exposures (Zober et al, 1994). The biological monitoring data and the results of the epidemiology study (in a separate memo from Ruth Allen) are used to characterize the results of the risk assessment (see Section 2.c for further information regarding the epidemiology study). The submitted exposure monitoring studies can be identified by the following information:

C **EPA MRID 423424-01:** *Worker Mixer/Loader, Applicator Exposure to Ronilan WP*, Sponsor: BASF Corporation, P.O. Box 13528, Research Triangle Park, N.C.; Authors: A. Rotondaro and E. McKane, Pan-Agricultural Laboratories, Inc., Madera, California; BASF Study No. 92/5048, Pan-Ag Study No. EF-90-02 and AL-106; Completed 4/6/92.

C **EPA MRID 424831-01:** *Worker Mixer/Loader, Applicator Exposure to Ronilan DF*, Sponsor: BASF Canada, Inc., 345 Carlingview Drive, Toronto Ontario; Authors: A. Rotondaro and L. Schuster, Pan-Agricultural Laboratories, Inc., Madera, California; BASF Study No. 90064, Pan-Ag Study No. AE-91-504; Completed 9/3/92.

C **EPA MRID 424649-01:** *Freezer Storage Stability Study of Vinclozolin in Worker Exposure Sampling Media*, Sponsor: BASF Corporation, 26 Davis Drive, Research Triangle Park, N.C.; Author: L. Schuster, Pan-Agricultural Laboratories, Inc., Madera, California; BASF Study No. 92/5126, Pan-Ag Study No. AL-107; Completed 8/20/92. [This study is used to support the results of

EPA MRID 424831-01. It is not summarized below as these data are accounted for in the development of the PHED grading criteria for MRID 424831-01.]

A summary of the two vinclozolin-specific exposure studies is presented below for informational purposes:

EPA MRID 423424-01: Exposure during mixing/loading and application was monitored separately in this study during several different types of applications. A total of 62 exposure events (i.e., replicates) were monitored on 10 different days. A total of 32 mixer/loader replicates and 30 applicator replicates were monitored. Mixing/loading was monitored using wettable powders and open bags on 8 of the 10 test days (26 replicates) while the remaining 6 replicates were monitored using dry flowable formulations. Monitored mixing/loading events were intended to reflect preparation for several types of applications including aerial, airblast, and groundboom applications. Additionally, applicator exposure was monitored during groundboom and airblast applications using both open and closed cab equipment. The following table summarizes the design of this study:

Test Number	Vinclozolin Formulation	Location	Application Equipment	Cab Type	Crop Type	No. Replicates/Test	
						M/L	Applicator
1	50 WP	Easton, CA	Airblast	Open	Apricots	0	5
2	50 WP	Chowchilla, CA	Airblast	Closed	Apricots/ Plums/ Peaches	0	5
3	50 WP	Williamson, NY	Airblast	Open	Cherries	5	5
4	50 WP	Firebaugh, CA	Groundboom	Open	Bare Ground*	5	5
5	50 WP	Firebaugh, CA	Groundboom	Closed	Bare Ground*	5	5
6	50 WP	Huron, CA	Groundboom	Open	Lettuce	5	5
7	50 WP	Caruthers, CA	Aerial	N/A	N/A	3	0
8	50 WP	Fresno, CA	Aerial	N/A	N/A	3	0
9	50 DF	Caruthers, CA	Aerial	N/A	N/A	3	0
10	50 DF	Fresno, CA	Aerial	N/A	N/A	3	0

* Bare ground was used in the treatments during test numbers 4 and 5, respectively, because of a "lack of useable head lettuce and strawberry acreage on the central coast of California, [as a result] the two central coast tests were conducted in the San Joaquin Valley on bare ground. Approval was received from the California Department of Food and Agriculture before bare ground applications were made."

The theoretical application rate for all activities in this study was 1.0 lb active ingredient per acre. The application volumes for airblast and groundboom applications was 50 and 100 gallons per acre, respectively. Inhalation exposures were monitored using personal sampling pumps equipped with glass fiber filters. Dermal (nonhand) exposures were monitored using patches, whole-body dosimeters (short-sleeved tee-shirts on the upper body), and Aerosol swipes for the forearms. Hand exposures were monitored using handwashes. PHED grades (for the quality of the analytical recovery data) ranged from A to C Grade. Urine samples were also collected for 48 hours post-application. These samples were analyzed using a method that converted all contained metabolites to DCAD. These values were then presented as equivalents of the metabolite, BF352-25, a major urinary metabolite of vinclozolin which is supported by rat metabolism data (EPA MRIDs 41824307 and 41824308). Rat metabolism data also indicate that approximately 50 percent of vinclozolin was excreted in the urine after 5 days (i.e., range from 48 to 54 percent) after a single oral dose and that approximately 70 percent was excreted after an intravenous dose.

As indicated above, the Agency has used these data, as well as data from similar studies that are also included in PHED to calculate unit exposure values that are the basis of this assessment (i.e., included in the *PHED Surrogate Exposure Guide*, August 1998). PHED grades for this study (for the quality of the analytical recovery data) ranged from A to C Grade. It is the policy of the Agency to integrate data from individual studies for use in the risk assessment process with other similar data. The biological monitoring data from this study were found to be inconclusive for the purposes of quantitative risk assessment. Therefore, these data were used only for qualitative risk characterization purposes. The data generated in this study (both passive dosimetry and biological monitoring) are presented in Appendix B of this document.

EPA MRID 42483101: The purpose of this study was to quantify exposure levels during mixing/loading, aerial application, and flagging activities on canola in Canada. Four field trials were completed in Starbuck and High Bluff, Manitoba, Canada on canola. In each trial, a mixer/loader, pilot (applicator), and flagger were monitored. Therefore, a total of twelve replicates were completed, 4 for each job function or task. Fixed-wing aircraft were used to apply vinclozolin to canola at the highest labeled rate, 1.0 kilogram (0.5 kilograms active ingredient) per hectare in approximately 40 liters per hectare (i.e., ~0.45 lb ai/acre and 4.3 gallons per acre). The average amount of active ingredient handled was 171 kilograms over each trial (i.e., 376 lb ai).

Each test subject "wore clothing and protective equipment that was in compliance with the proposed label, coveralls or long pants and long-sleeved shirts. Mixer/loaders also wore goggles, protective gloves and chemical resistant boots." The coveralls were a cotton/polyester blend. Dermal exposure [excluding hands] was monitored using modified Durham-Wolfe patch dosimeters, upper whole-body dosimeters, and forearm swipes. The hand exposure of mixer/loaders and applicators was measured using detergent handwashes. Inhalation exposure was monitored using personal air-sampling pumps and GFF filter cassettes. Urine samples were also collected for 48 hours post-application. These samples were analyzed using a method that converted all contained metabolites to DCAD. These values were then presented as equivalents of the metabolite, BF352-25, a major urinary metabolite of vinclozolin which is supported by rat metabolism data (EPA MRIDs 41824307 and 41824308). Rat metabolism data also indicate that approximately 50 percent of vinclozolin was excreted in the urine after 5 days (i.e., range from 48 to 54 percent) after a single oral dose and that approximately 70 percent was excreted after an intravenous dose.

As indicated above, the Agency has used these data, as well as data from similar studies that are also included in PHED to calculate unit exposure values that are the basis of this assessment (i.e., included in the *PHED Surrogate Exposure Guide*, August 1998). PHED grades (for the quality of the analytical recovery data) ranged from C to E Grade. It is the policy of the Agency to integrate data from individual studies for use in the risk assessment process with other similar data. The biological monitoring data from this study were found to be inconclusive for the purposes of quantitative risk assessment. Therefore, these data were used only for risk characterization purposes. From a qualitative perspective, the investigators indicated "the results of biological monitoring was consistent with those of dermal and inhalation monitoring with passive dosimetry. Workers with higher dermal vinclozolin residues generally had higher concentrations of vinclozolin in their urine." The data generated in this study (both passive dosimetry and biological monitoring) are presented in Appendix C of this document.

Pesticide Handlers Exposure Database (PHED): PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored application events (i.e., referred to as replicates).

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (e.g., mixing/loading, applying), formulation type (e.g., wettable powders, granulars), application method (e.g., aerial, groundboom), and clothing scenarios (e.g., gloves, double layer clothing).

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g., chest upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body. The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. It should also be noted that distributional analyses of the data contained in PHED are not done for the risk assessment process because the available data do not lend themselves to this kind of analysis.

To add consistency to the values produced from this system and to ensure quality control, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Appendix A/Table 1. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. The Agency has developed a series of tables of standard unit exposure values (i.e., representing the "best fit" for each dataset) for many occupational scenarios that can be utilized to ensure consistency in exposure assessments.

In addition to PHED, the application rate and daily amount treated (usually acres per day) are also key elements in the calculation of handler exposures. A range of application rates, derived from vinclozolin labeling and the data from the QUA, serves as the basis for this assessment. Maximum application rates range from up to 1 pound of active ingredient per acre in agricultural settings and up to 1.35 pounds of active ingredient per acre on some ornamentals and turf. In other cases where handheld equipment and other application methods are used, rates can vary widely due to the *ad libitum* nature of the application method. For these application methods, the highest concentration allowed is 0.015 pounds of active ingredient per gallon. The recent QUA was used to establish average application rates for various agricultural crops. The range of average application rates calculated in this analysis all appeared to be less than 1 lb ai/acre for each agricultural crop (i.e., most are around 0.5 lb ai/acre). Wherever available, both maximum and average application rates are used in each assessment.

The amount treated per day, usually expressed as the number of acres treated per day, is another critical factor in the exposure calculations for handlers. The Agency typically uses acres treated per day values that are thought to represent 8 solid hours of application work for specific types of application equipment. The Agency has used the same default values for acres treated per day for several years. These values were based on data included in PHED, consideration of agricultural engineering principles, and use and usage information. Through NAFTA (North American Free Trade Agreement) auspices, there is currently an initiative underway to harmonize the acres treated per day values used for the purposes of risk assessment. The values currently used by the Agency are similar or equivalent to those being discussed in the NAFTA working group. The actual values, specific to each scenario in the risk assessment, are presented below.

In addition to the information presented above, the following assumptions and factors were used in order to complete this exposure assessment:

- An average occupational work day interval represents 8 hours per workday. The definition of a workday has been used by the Agency to define the number of acres that could be treated based on the application method and application site. The values used by the Agency to represent the amount of acres that can be treated in a day (or application volumes as appropriate) for each scenario include:

  <u>For Occupational Treatments on Ornamental Use Sites (*+):</u>
  (1a) 350 acres worth of spray solution prepared when mixing/loading dry flowables for aerial applications;
  (1b) 40 acres worth of spray solution prepared when mixing/loading dry flowables for airblast applications;
  (1c) 40 acres worth of spray solution prepared when mixing/loading dry flowables for groundboom applications;
  (1d) 1000 gallons of spray solution prepared when mixing/loading dry flowables for high-pressure handwand applications;
  (1e) 100 gallons of spray solution prepared when mixing/loading dry flowables for dipping applications;
  (1f) 5 gallons of spray solution prepared when mixing/loading dry flowables for thermal fogging applications;
  (1g) 5 acres worth of spray solution prepared when mixing/loading dry flowables for low pressure/high

volume turfgun applications;
(2a) 350 acres worth of spray solution prepared when mixing/loading liquid flowables for aerial applications;
(2b) 40 acres worth of spray solution prepared when mixing/loading liquid flowables for airblast applications;
(2c) 40 acres worth of spray solution prepared when mixing/loading liquid flowables for groundboom applications;
(2d) 1000 gallons of spray solution prepared when mixing/loading liquid flowables for high-pressure handwand applications;
(2e) 100 gallons of spray solution prepared when mixing/loading liquid flowables for dipping applications;
(2f) 5 gallons of spray solution prepared when mixing/loading liquid flowables for thermal fogging applications;
(2g) 5 acres worth of spray solution prepared when mixing/loading liquid flowables for low pressure/high volume turfgun applications;
(3a) 350 acres worth of spray solution prepared when mixing/loading extruded granules for aerial applications;
(3b) 40 acres worth of spray solution prepared when mixing/loading extruded granules for airblast applications;
(3c) 40 acres worth of spray solution prepared when mixing/loading extruded granules for groundboom applications;
(3d) 1000 gallons of spray solution prepared when mixing/loading extruded granules for high-pressure handwand applications;
(3e) 100 gallons of spray solution prepared when mixing/loading extruded granules for dipping applications;
(3f) 5 gallons of spray solution prepared when mixing/loading extruded granules for thermal fogging applications;
(3g) 5 acres worth of spray solution prepared when mixing/loading extruded granules for low pressure/high volume turfgun applications;
(4) 40 acres when applying sprays with an airblast sprayer;
(5) 40 acres when applying sprays with a groundboom sprayer;
(6) 350 acres when applying sprays with a fixed-wing aircraft (also accounts for helicopter applications);
(7) 1 greenhouse when completing thermal fogging in greenhouses;
(8) 100 gallons of spray solution when applying by dipping cut flowers, nurserystock, or bulbs and corm;
(10) 1000 gallons of spray solution when applying using a high-pressure handwand sprayer;
(11) 5 acres when applying using a low-pressure/high-volume turfgun sprayer;
(12) 40 gallons of spray solution when mixing/loading/applying using a low-pressure handwand sprayer;
(13) 40 gallons of spray solution when mixing/loading/applying using a backpack sprayer; and
(14) 350 acres when flagging for aerial spray application.

For Occupational Uses In Agriculture on Terrestrial Crops/Targets (*+):

(1a) 350 acres worth of spray solution when mixing/loading dry flowables for aerial and chemigation applications;
(1b) 40 acres worth of spray solution when mixing/loading dry flowables for airblast applications;
(1c) 80 acres worth of spray solution when mixing/loading dry flowables for groundboom applications;
(1d) 100 gallons of solution when mixing/loading dry flowables for greenhouse forcing tray applications;
(2a) 350 acres worth of spray solution when mixing/loading liquid flowables for aerial applications;
(2b) 40 acres worth of spray solution when mixing/loading liquid flowables for airblast applications;
(2c) 80 acres worth of spray solution when mixing/loading liquid flowables for groundboom applications;
(3a) 350 acres worth of spray solution when mixing/loading extruded granules for aerial and chemigation applications;
(3b) 40 acres worth of spray solution when mixing/loading extruded granules for airblast applications;
(3c) 80 acres worth of spray solution when mixing/loading extruded granules for groundboom applications;
(4) 40 acres when applying sprays with an airblast sprayer;
(5) 80 acres when applying sprays with a groundboom sprayer;
(6) 350 acres when applying sprays with a fixed-wing aircraft (also accounts for helicopter applications);
(9) 100 gallons when applying to chicory/endive rootstock in forcing tray;
(12) 40 gallons of spray solution when mixing/loading/applying using a low-pressure handwand sprayer;
(13) 40 gallons of spray solution when mixing/loading/applying using a backpack sprayer; and
(14) 350 acres when flagging for aerial spray application.

- As indicated above, the Agency has developed a series of unit exposures that can be used in risk assessments for different application equipment and varying levels of protection. Due to a lack of empirical, scenario-specific data, unit exposures are sometimes calculated using generic protection factors that are intended to represent the protectiveness of various risk mitigation options (i.e., the use of PPE or Personal Protective Equipment and engineering controls). PPE protection factors include those representing layers of clothing (50%), chemical-resistant gloves (90%), and respiratory protection (80 to 90% depending upon mitigation selected). Engineering controls are generally assigned a protection factor of 98 percent. Engineering controls may include closed mixing/loading systems for liquids, closed cabs/cockpits, and closed gravity fed loading systems for granulars. Adjustments to exposure values using protection factors are made using the following equation and are completed only in lieu of scenario-specific monitoring data (PF = Protection Factor expressed as a percent reduction):

  PF Adjusted Exposure = (1-(PF/100)) * (Nonadjusted Exposure Value)

  Baseline occupational assessments and homeowner applicator unit exposures are typically calculated based on empirical data that is reflective of the scenario. In other words, the empirical data in PHED used to generate exposure values are generally monitoring data that were generated in which the individuals tested were wearing clothing similar to the occupational baseline (long pants and long-sleeved shirt) and the homeowner applicator (short pants and short-sleeved shirts).

- For the short-/intermediate-term non-cancer risk assessments, the average body weight of an adult handler is 60 kg because the NOAELs used for the short- and intermediate-term assessments were selected based on developmental concerns for female populations (ages 13+). This body weight value represents that of adult females in the general population. For the chronic noncancer assessments and the cancer risk assessments, the average body weight of an adult handler is 70 kg because the biological mechanism that leads to the chronic toxicity or the development of cancer is not sex-specific. This body weight value represents that of adults, both male and female, in the general population.

- Calculations are completed for a range of maximum application rates for various crop groupings in order to bracket handler risk levels associated with specific application equipment. Where available, typical application rates from the recent *Quantitative Usage Analysis* (QUA) were also used in the calculations.

- Risk mitigation options for occupational handlers are based on the Worker Protection Standard and the criteria established by the Agency in the guidance for the Pesticide Handlers Exposure Database (i.e., extra layers of clothing, chemical-resistant gloves, respirators, closed-systems, etc.).

- The Agency believes that the vast majority of exposures occur in short- and intermediate-term durations of exposure (i.e., up to 6 months of continuous exposure with most exposures being a month or less in duration). However, for complete stewardship and for a more informed risk management decision, the Agency has also completed a chronic exposure assessment (i.e., for scenarios with greater than 180 days of continuous exposure) for selected exposure scenarios where it is believed that exposures of these durations could occur. The Agency does not believe that chronic exposures occur in agriculture except for some uses in the ornamental industry. For example, it is likely in the production of cut flowers such as roses an individual could prepare and use dipping solutions or foliar sprays prior to cold storage and transit on a daily basis. Short-/Intermediate-term non-cancer risks (i.e., MOEs) have been calculated for all exposure scenarios and only for specific scenarios for which the Agency believes chronic exposures occur. If the Agency does not believe that a chronic duration assessment is needed for specific scenarios, then no value will have been calculated and included in the tables in Appendix A.

- A cancer risk assessment using both a threshold (MOE) approach and linear low-dose extrapolation is required for vinclozolin because the available cancer mechanism data indicate that this approach is appropriate only for exposures of extended duration. The appropriate absorbed dose to be used in these assessments is the LADD (Lifetime Average Daily Dose) in which exposures over an individual's lifetime are amortized. In order to calculate LADD values for vinclozolin exposures, the Agency has used the following inputs for exposure frequency (number of events per year), average length of lifetime, and number of years involved in an activity. In all assessments a lifetime duration value of 70 years has been used per Agency policy along with the working life duration of 35 years. Frequency values are also required for risk assessment purposes appropriate to each type of application method and crop/target evaluated. These frequency values are intended to represent the average annual frequency of application events (i.e., exposures) on an annual basis. In this case, since cancer is a concern only for individuals who are exposed over an extended duration, the frequency values used for all assessments (i.e., 90 and 180 days) represent exposures for a very small segment of the vinclozolin user population and are not intended to reflect typical use patterns as is the case with most cancer risk assessments. The Agency has completed the cancer risk assessment only for a selected small segment of the population where the exposure patterns fit criteria of extended periods of exposure as defined by the available mechanism data.

C No exposure data are available to assess exposures for scenarios 7, 8, and 9. Exposure scenario 7 encompasses application by thermal fogging in greenhouses. Even though no direct monitoring data were available, a screening level risk assessment approach was used based on the theoretical airborne concentration, which involved calculating airborne concentrations using the application rate to assess the risks and consider respiratory protection. This calculation is intended to reflect the exposures one would receive either turning on the fogging equipment or entering the treated greenhouse to vent the facility which is considered part of the application process. The Agency believes that exposures occur that are within the scope of scenarios 8 (i.e., application by dipping cut flowers, nurserystock, bulbs or corm) and 9 (i.e., application to chicory/endive rootstock in forcing trays). However, the Agency has no direct monitoring data or screening level approach to complete the assessments for these scenarios. As a result, the Agency has carried these scenarios through the assessment process to acknowledge that these exposures are of concern because of a lack of appropriate monitoring data.

C Application scenarios for golf courses have not been considered as a separate series of exposure scenarios in this assessment. Rather, the exposures and risks associated with this use pattern are accounted for by the scenarios generically considered for applications to turf. For example, the risks associated with the use of a high pressure handwand or low pressure/high volume turfgun would also represent the risks associated with the golf course use pattern.

C Application scenarios for greenhouse uses have not been considered as a separate series of exposure scenarios in this assessment except for some specialized uses such as cut flower dipping. Rather, the exposures and risks associated with this use pattern are accounted for by the scenarios generically considered for applications using various handheld application methods such as the high pressure handwand or low pressure/high volume turfgun.

iv. Post-Application Exposure Scenarios

Vinclozolin can be used in agriculture on a variety of field crops, tree fruits, small fruits, and specialty items such as chicory. Vinclozolin can also be used in the ornamental industry for the production of cut flowers, woody and herbaceous ornamental plants, nursery products such as bulbs and rootstock, and the production/maintenance of turf from sodfarms and in other areas such as golf courses. As a result, individuals can be exposed by entering previously treated areas and engaging in activities that could contribute to exposure. The Agency is concerned about exposures one could receive in the workplace or in other areas that are frequented by the general population, including residences from turf transported from sodfarms. The purpose of this section of the document is to explain how post-application exposure scenarios were developed for each setting where vinclozolin can be used. Exposure scenarios can be thought of as ways of categorizing the kinds of exposures that occur related to the use of a chemical. The use of scenarios as a basis for exposure assessment is very common as described in the *U.S. EPA Guidelines For Exposure Assessment* (U.S. EPA; Federal Register Volume 57, Number 104; May 29, 1992).

The Agency uses the term "post-application" to describe those individuals who can be exposed to pesticides after entering areas previously treated with pesticides and performing certain job tasks or activities (also often referred to as reentry exposure). As with the handler risk assessment scenarios described above in Section 2.b.ii, the agency believes that there are distinct job tasks that occur in areas previously treated with vinclozolin and also non-work related activities in treated areas that may contribute to exposure (e.g., children playing on turf). The Agency also believes that the resulting exposures can vary depending upon the specifics of each task or activity and the levels of chemical residue available in the environment. The nature of the treated area (e.g., crop foliage level) and the duration of activity of the individual can also cause exposure levels to differ in a manner specific to each setting considered.

The agency uses a concept known as the *transfer coefficient* to numerically represent the post-application exposures one would receive (i.e., generally presented as cm^2/hour). The transfer coefficient concept has been established in the scientific literature and through various exposure monitoring guidelines published by the U.S. EPA and international organizations such as Health Canada and OECD (Organization For Economic Cooperation and Development). Transfer coefficients are also the basis of the Agricultural Reentry Task Force, of which, the BASF Chemical Company is a member. The transfer coefficient is essentially a measure of the contact with a treated surface one would have while doing a task or activity. These values are defined by calculating the ratio of an exposure for a given task or activity to the amount of pesticide on leaves (or other surfaces) that can rub off on the skin resulting in an exposure. For post-application exposures, the amounts that can rub off on the skin are measured using techniques that specifically determine the amount of residues on treated leaves or other surfaces (referred to as transferable residues) rather than the total residues contained both on the surface and absorbed into treated leaves. Transfer coefficients can be illustrated by the following example. Consider two vegetable fields where the amount of chemical on treated leaf surfaces that can rub off on the skin is the same. One field has been treated with chemical A while the other field has been treated in a similar manner with chemical B. If an individual harvests vegetables for a day in each field, the exposures the individual would receive would be similar. The transfer coefficient would also be similar for each field and chemical because the ratio of exposure to residue would be the same. If the same individual would do another activity in those fields such as scout the vegetables for pests or tie the vegetables, the exposures would be different as would the resulting transfer coefficients because the activity that resulted in the exposures is different. In this example, three distinct transfer coefficients could be determined for vegetable crops: harvesting; scouting; and tying. The Agency has developed a series of standard *transfer coefficients* that are unique for variety of job tasks or activities that are used in lieu of chemical- and scenario-specific data.

Like with the handler risk assessment process, the first step in the post-application risk assessment process is to identify the kinds of individuals that are likely to be exposed to vinclozolin after application. In order to do this in a consistent manner, the Agency has developed a series of general descriptions for tasks that are associated with post-application exposures. The Agency also considers whether or not individuals are exposed to pesticides as part of their employment (referred to as occupational risk assessments) or if they are individuals who are exposed to pesticide products in and around their residences or other areas frequented by the general public. Tasks associated with post-application exposures can generally be categorized using one of the following terms:

- **Post-application Workers:** these individuals perform tasks as part of their employment that cause them to enter areas previously treated with a pesticide and complete these tasks. Common examples include: agricultural harvesters, scouting activities in agriculture, greenhouse workers (e.g., harvesters and packers).

- **Residential (homeowner) Adults:** these individuals are members of the general population that are exposed to chemicals by engaging in activities where vinclozolin applications have occurred such as golf courses. These kinds of exposures are attributable to a variety of activities and usually addressed by the Agency using a representative activity that results in a conservative exposure calculation for the exposed population. In this case, the exposure of golfers on treated greens and tees is thought to address exposures of nonoccupationally exposed adults on treated turf (keeping in mind that vinclozolin use on residential turf and parklands is prohibited).

- **Residential Children:** children (infants and toddlers are the representative or sentinel population) are members of the general population that can be exposed to chemicals by engaging in activities in areas not limited to their residence previously treated with a pesticide. These kinds of exposures are attributable to a variety of activities such as playing on treated turf. [Note: For vinclozolin, the turf assessment is intended to define the amount of time prior to sodfarm harvest that vinclozolin applications can be made as treated turf from sodfarms can be sold and used in a residential environment or other areas where children can be exposed.]

There are individuals who are potentially exposed to vinclozolin that fit into each of the categories described above. Therefore, the vinclozolin post-application exposure/risk assessment contains exposure scenarios in each category described above.

The next step in the risk assessment process is to define how and when chemicals are applied in order to determine the level of transferable residues to which individuals could be exposed over time (i.e., to aid in the design of studies and to refine the risk assessment). Wherever available, use and usage data are used in this process to define values such as application rates and application frequency. The Agency always completes risk assessments using maximum application rates for each scenario because what is possible under the label (the legal means of controlling pesticide use) must be evaluated, for complete stewardship, in order to ensure that the Agency has no concern for the specific use. Additionally, whenever the Agency has additional information, such as minimum application rates or application frequency, it uses the information to further evaluate the overall risks associated with the use of the chemical (e.g., only a single application was considered for the vinclozolin post-application risk assessment). In order to define the amount of transferable residues to which individuals can be exposed, the Agency relies on chemical- and crop-specific studies as described in the Agency guidelines for exposure data collection (*Series 875, Occupational and Residential Exposure Test Guidelines: Group B - Postapplication Exposure Monitoring Test Guidelines*). For instances when transferable residue data are not available, the Agency developed a standard modeling approach that can also be used to predict transferable residues over time. However, for vinclozolin, transferable residue data are available for peaches, strawberries, and on turf which have been used in this assessment to calculate the resulting exposures and risks. Exposure data using the Jazzercize method were also generated on turf after a vinclozolin application. These data have been used to calculate exposures to children on turf. Where transferable residue and exposure data were not available, the Agency bridged from the existing data as appropriate or used guidance from *the SOPs For Residential Exposure Assessment* to complete the risk assessment.

Defining the activities that could lead to exposures related to the use of the chemical is also a critical aspect of the process. Generally, this can be a difficult aspect of the risk assessment process in that many activities are plausible and dynamics of the population of interest constantly change. As such, the Agency currently uses scenarios that generically represent many activities related to the populations of concern to calculate exposures. Vinclozolin labels allow for occupational uses on ornamentals, in agriculture, and on turf where exposures to the general population can occur (i.e., golf courses and by treated sod being used in a residential setting). Therefore, people in their jobs can be exposed as well as both children and adults in areas frequented by the general public. The occupational exposures considered in this assessment reflect the kinds of jobs/tasks that would be associated with the cultural practices on crops where vinclozolin is used as well as on ornamentals/nursery products where vinclozolin can be used (e.g., harvesting snapbeans or sod and cutting/harvesting roses). Children's exposures are not considered after a direct use in a residential environment but were considered in order to establish the time required before the harvesting of treated sod to allow for adequate time for residues to dissipate prior to placement in a residential environment. Adult non-occupational exposures were considered in the assessment for golf course uses. The Agency considered both low exposure (e.g., scouting and light crop maintenance activities) and higher exposure activities (e.g., harvesting) for the occupational uses of vinclozolin in both agriculture and for ornamental production. For the nonoccupational exposures, the Agency considered golfing for adults and children engaged in heavy play outdoors using the Jazzercize model. The Agency's *SOPs For Residential Exposure Assessment* was used to provide guidance for calculating the non-occupational exposures of adults and children as appropriate (e.g., for inputs where chemical- and scenario-specific data were not available) in conjunction with the available exposure data.

Next, assessors must understand how exposures to vinclozolin occur (i.e., frequency and duration) and how the patterns of these occurrences can alter the effects of the chemical in the population after being exposed (referred to as dose response). The Agency believes that vinclozolin exposures can occur over a single day or up to weeks at a time even though many crops, golf course turf, and ornamentals are likely treated only a couple of times per season. Some exposures (e.g., for certain greenhouse uses such as cut flowers) are even thought to be chronic in nature due to the persistence of vinclozolin and the frequency of exposure events (e.g., harvesting cut flowers such as roses in greenhouses occurs very frequently). This approach is also supported by the length of time that residues took to decline in the available vinclozolin dislodgeable foliar residue studies and the fact that several areas within a work environment may be treated at different times. For example, parts of agricultural fields within a localized area where there is an ongoing need for handlabor activities might be treated over several weeks because of an ongoing infestation and individuals may move between treated areas. Typically, the Agency categorizes non-dietary exposures for use in non-cancer risk assessments based on the duration of exposure using generic criteria that include intervals of one week or less (short-term exposures), periods of seven days up to six months (intermediate-term exposures), and periods of longer than 180 days of exposure (chronic exposures). In cancer risk assessments, the Agency typically uses a linear low dose extrapolation method based on the Q_1* value developed with the dose response data for the chemical of concern. The purpose of these classifications is to provide a basis for selecting toxicological endpoints for chemicals that can be modified based on the available toxicity data. A chemical can have different effects based on how long or how often a person is exposed. The toxicity of chemicals can vary based on how a person is exposed. In this case, a single endpoint is appropriate for completing the short- and intermediate-term exposure duration assessments in adults based on decreased ventral prostate weights observed in a rat developmental study. Similarly, for infants and children, a single endpoint based on a delayed puberty in a rat developmental study, has also been used to complete the assessment. Vinclozolin is also somewhat unique in that the Agency believes that there are exposure scenarios that are of chronic duration. For the chronic noncancer assessment, regardless of the population of concern, an endpoint based on lesions in the lungs, liver, ovaries, and eyes was selected. In this case, available cancer mechanism data indicate that the linear low-dose approach is appropriate but only for exposures of extended duration. For characterization purposes, cancer risk values were also calculated using the MOE approach based on an oral NOAEL identified in a cancer study -- a range of MOE values are presented in the summary of this document in conjunction with the corresponding Q_1* calculated cancer risks for characterization purposes given the scientific debate over appropriate uncertainty factors for cancer MOE calculations. The toxicology database for vinclozolin indicates that the Agency does not need to separately consider exposures to the skin and exposures via inhalation because the effects and the dose levels at which effects occur are the same based on whether vinclozolin gets on skin or it is inhaled (i.e., short- and intermediate-term effects were identified from an oral administration developmental toxicity study, chronic effects and cancers were also found in oral administration studies). Inhalation exposures are thought to be negligible in outdoor post-application scenarios because of the low vapor pressure and because the empirical data have also generally shown post-application inhalation exposures to be negligible. As such, inhalation exposures are not considered in this assessment. Hand-to-mouth exposures also were not considered in this assessment because the only scenarios where this exposure would be considered is for children on treated sod (i.e., a short-term exposure calculation) and no endpoint was selected for this assessment (i.e., acute dietary analyses were not completed as no appropriate endpoint was selected as indicated in November 1999 HIARC document).

The use of personal protective equipment or other types of equipment to reduce exposures for post-application workers is not considered a viable alternative for the regulatory process except in specialized situations (e.g., a rice scout will wear rubber boots in flooded paddies). As such, an administrative approach is used by the Agency to reduce the risks and is referred to as the *Restricted Entry Interval* or REI. The REI is a measure of the time it takes for residue levels to decline to a point that entry into a previously treated area and engaging in a task or activity would not result in exposures that exceed the Agency's level of concern. REIs are generally established in the risk assessment process on a chemical-, crop-, and activity-specific basis. REIs are not considered a viable regulatory tool for reducing exposures and risks in the residential environment (i.e., for the general population). Therefore, for chemicals used in the residential environment or any other areas where the general population can be exposed, regulatory risk management currently considers the risks associated with a chemical on the day it is applied or as part of an aggregate exposure assessment should the single day risks be of no concern. The assessment for vinclozolin is also somewhat unique in that the Agency calculated the amount of time that is required prior to harvesting sod in the residential assessment for infants and children instead of the typical application day assessment. This type of assessment was completed because vinclozolin is not labeled for direct application on residential turf and defining the amount of time for adequate residue dissipation prior to harvesting sod will preclude treated sod from being placed in residential environments too soon after application.

Given all of the above information, several scenarios have been developed for exposures related to vinclozolin use. These scenarios serve as the basis for this risk assessment. Exposure scenarios were developed for occupational uses in agricultural settings and for residential uses of vinclozolin. The scenarios considered in this assessment are presented below:

<u>For Uses In Agriculture Resulting in Occupational Exposures (*):</u>
Based on the anticipated vinclozolin use patterns and current labeling, four major postapplication exposure scenarios were assessed using surrogate transfer coefficients commonly used by the Agency, the chemical-specific transfer coefficients calculated based on chemical-specific exposure and concurrent dislodgeable foliar residue dissipation data, and the chemical-specific dislodgeable foliar residue dissipation data described below. These assessments were also completed based on the guidance provided in the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines (7/24/97 Version).* The four scenarios assessed include:

(1) adults scouting in canola, onions, lettuce, and other low row crops*;

(2) adults harvesting lettuce*;

(3) adults scouting raspberries, and snapbeans as well as harvesting raspberries and low growing snapbeans*; and

(4) adults harvesting onions, kiwi, and trellised snapbeans*.

[*These exposures were assessed to determine Restricted Entry Interval, also may represent other activities that are completed in the specific crops for which vinclozolin is labeled -- refer to Exposure SAC Policy 003 for further information about crop groupings and representative activities. Some occupational exposures resulting from the treatment of agricultural commodities such as chicory/endive uses have not been assessed and are not represented by the above scenarios as there is no approach for completing these types of calculations.]

<u>For Occupational Uses On Ornamentals Resulting in Exposures to the General Population (#):</u>
The Agency has determined that there are likely post-application exposures to the general population because vinclozolin can be applied to turf on golf courses and also on sod that can end up in a residential environment. The calculations for golfer exposure are based on the available turf transferable residue data, current Agency policies for assessing golfer exposures, and the label restriction for use on golf greens and tees. The sodfarm uses has been evaluated to assess the amount of time prior to harvest that is required for residues to dissipate to levels where risks to children are expected to be above the Agency's level of concern. The calculations for children on treated sodfarms turf are based on the available turf transferable residue data and concurrent Jazzercize exposure data. These assessments were also based, as appropriate, on the guidance provided in the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines (7/24/97 Version)* and the *Draft: Standard Operating Procedures (SOPs) for Residential Exposure Assessment (12/11/97 Version)*. The two scenarios assessed include:

(1) adults golfing on treated greens and tees; and

(2) toddlers after contact with treated sodfarm turf.

[# Note: administrative controls for risk mitigation such as Restricted Entry Intervals are not applicable, these exposures were calculated solely for determining the amount ot time required prior to harvest and placement of treated turf into a residential environment and to determine the acceptability of the golf course use pattern.]

<u>For Uses On Ornamentals Resulting in Occupational Exposures (*):</u>
Based on the anticipated vinclozolin use patterns and current labeling, four major postapplication exposure scenarios were assessed using surrogate transfer coefficients commonly used by the Agency, the chemical-specific transfer coefficients calculated based on chemical-specific exposure and concurrent residue dissipation data described below. These assessments were also completed based on the guidance provided in the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines (7/24/97 Version)*. The four scenarios assessed include:

(1) adults mowing and maintaining treated turf*;

(2) adults sorting and packing ornamentals in a greenhouse*;

(3) adults irrigating ornamentals*;

(4) adults harvesting or placing sod, cutting flowers in a greenhouse*, and

(5) adults reentering fogged greenhouses for aeration of the facility (inhalation assessment only qualitatively assessed as similar assessment for completion of fogging activities completed above for handlers also applies to this scenario -- see Section 2.b above).

[*Note: Risks assessed to determine Restricted Entry Interval, also may represent other activities that are completed in the specific crops for which vinclozolin is labeled -- refer to Exposure SAC Policy 003 for further information about crop groupings and representative activities. Some occupational exposures resulting from the treatment of ornamentals such as cut flower dipping or the treatment of barefoot nurserystock have not been assessed and are not represented by the above scenarios as there is no approach for completing these types of calculations.]

v. Post-Application Exposure and Risk Assessment

As described above, the Agency considers how chemical exposures occur including how chemicals enter the body (because the toxic effects can be different) such as absorption through the skin or by inhalation, both of these kinds of exposures are typically considered for handlers. However, in this post-application assessment, the Agency has focused on the predominant exposure pathways which are thought to be exposures to the skin (i.e., dermal) and exposures from the mouthing behaviors of children in cases where exposures to the general population can occur. Inhalation exposures were also considered but are expected to be negligible because of the potential for dilution in settings where vinclozolin is used and the historical data that indicates these kinds exposures to be minimal.

The post-application risk assessment for vinclozolin has been developed using chemical-specific dislodgeable foliar residue data and chemical-specific post-application exposure monitoring data from strawberries, stone fruit, and turf. These data have been used as the basis for the assessment in conjunction with standard Agency inputs for exposure and risk assessment purposes as appropriate (e.g., duration and transfer coefficients for certain activities). All post-application exposure and risk calculations are presented below. Additionally, the specifics of each dataset and how each was used in the risk assessment is presented.

In order to clearly present the current post-application exposure assessment, it is necessary to present the data upon which it is based. The studies used to determine the dislodgeable foliar residue levels and human exposure levels for risk assessment purposes can be identified by the following information:

Monitoring Data For Peaches:

- **MRID 42830001:** Kludas, R.; Schimelfining, S. (1993) Dissipation of Dislodgeable Foliar Residues of Vinclozolin (Ronilan DF Fungicide) Applied to Orchards California and Georgia Sites: Lab Project Number: 92092: ER93017: 92086. Unpublished study prepared by Pan-Agricultural Labs, Inc. 122 p.

- **MRID 43505901:** Morris, M.; Schimelfining, S. (1994) Dissipation of Dislodgeable Foliar Residues of Vinclozolin (Ronilan DF Fungicide) Applied to Orchards Pennsylvania Site (One of Three Sites): Lab Project Number: 94/5177: 92086: 92234. Unpublished study prepared by Pan-Agricultural labs, Inc. 99 p.

- **MRID 42830002:** Rosenheck, L.A., Schimelfining, S.D., Clark, J.R. (1993) *Worker Re-entry Exposure While Harvesting Stone Fruit Treated With Ronilan DF Fungicide in California* Sponsor: BASF, Inc., 2520 Meridian Parkway, P.O. Box 13528, Durham N.C.; Conducting Laboratory: Pan-Agricultural Laboratories, Inc., Madera, California; BASF Study No. 92092, BASF Report No. ER93012, Pan-Ag Study No. 92086.

Monitoring Data For Strawberries:

- **MRID 43013004:** Rosenheck, L.; Schimelfining, S.; Clark, J. (1993) Dissipation of Dislodgeable Foliar Residues of Vinclozolin (Ronilan DF Fungicide) Applied to Strawberry: Lab Project Number: 92092: ER93015: 92086. Unpublished study prepared by Pan-Agricultural Labs, Inc. and BASF Corp. 183p.

- **MRID 43013005:** Rosenheck, L.; Schimelfining, S.; Clark, J. (1993) Dissipation of Dislodgeable Soil Residues of Vinclozolin (Ronilan DF Fungicide) Applied to Strawberry: Lab Project Number: 92092: ER93016: 92086. Unpublished study prepared by Pan-Agricultural Labs, Inc. and BASF Corp. 134 p.

- **MRID 43013003:** Rosenheck, L.; Schimelfining, S.; Clark, J. (1993) Worker Re-entry Exposure While Harvesting Strawberries Treated with Ronilan DF Fungicide in California: Lab Project Number: 93/5140: 92092: ER93013. Unpublished study prepared by Pan-Agricultural Labs, Inc. and BASF Corp. 179 p.

Monitoring Data For Turf:

- **MRID 43343701:** Kludas, R.; Schimelfining, S. (1994) Foliar Dislodgeable Residues of Vinclozolin (Ronilan 50% DF) in Turf, California and Pennsylvania Sites: Lab Project Number: 92086: 92092: ER93019. Unpublished study prepared by Pan-Agricultural Labs, Inc. 241 p.

- **MRID 43528701:** Sandberg, C.; Schimelfining, S. (1994) Foliar Dislodgeable Residues of Vinclozolin (Ronilan 50 (percent) DF) in Turf Florida Site (one of three sites): Lab Project Number: 94/5178: 92092: ER93020. Unpublished study prepared by Pan-Agricultural Labs, Inc. in cooperation with Agvise Labs. and Weed Systems, Inc. 181 p.

- **MRID 43343702:** Rosenheck, L.; Schimelfining, S. (1994) Evaluation of Turf Re-entry Exposure in California to Broadcast Application of Ronilan DF: Lab Project Number: 92092: 92086: ER93011. Unpublished study prepared by Pan-Agricultural Labs, Inc. 238 p.

Appendices D, E, and F include tables that summarize the data generated in these studies. Appendix D contains the chemical-specific dislodgeable foliar residue dissipation data that were generated for the use of vinclozolin on peaches. Appendix D also contains the calculations completed by the Agency using these data to define predicted DFR levels using each of the 5 dissipation methods described above. Appendix E contains the chemical-specific dislodgeable foliar residue dissipation monitoring data that were generated for the use of vinclozolin on strawberries. Appendix E also contains the calculations completed by the Agency using these data to define predicted DFR levels. Appendix F contains the chemical-specific dislodgeable foliar data and concurrent exposure monitoring data that were generated for the use of vinclozolin on turf. Appendix F also contains the calculations completed by the Agency using these data to define predicted DFR levels and transfer coefficients. In order to better understand the data presented in these appendices, a brief summary of the referenced studies is included below along with any other explanations of the data as required.

Monitoring Data For Peaches:

- **MRID 42830001:** The dissipation of vinclozolin dislodgeable foliar residues after airblast application of Ronilan DF at 1.0 lb ai/acre to peaches in Georgia and California was quantified. Applications were made with an airblast sprayer using 50 gallons of water per acre. Dislodgeable foliar residue samples were collected using the standard approach with a Birkestrand leaf punch device and aqueous surfactant washing (i.e., the Iwata method). Duplicate samples were collected prior to and after the application then approximately 1, 2, 3, 7, 10, 14, 21, 28, 35, 42, 49, 56, and 63 days after application (i.e., 40 punches with a 1 inch diameter punch = 400 cm^2 per sample). Samples were dislodged and frozen on the day of collection. Field recovery samples were generated at each study site on 5 distinct sample collection days, on 3 days the solutions were prepared with hexane and on the other days the solutions were prepared with MTBE. Triplicate tank mix solution samples were also collected for each application. The application at the California site was completed on August 17, 1992. There was no recorded rainfall or foliar irrigation completed in the study (flood irrigation was completed every 10 days). The application at the Georgia site was completed on August 5, 1992. There was a total of 11.24 inches of rainfall and no irrigation over the course of the study in Georgia. The first rainfall event occurred 2 days after application with 0.7 inches of precipitation (2.44 inches in the first 14 days). The collected aqueous samples were analyzed by extraction with hexane in a separatory funnel followed by quantification by gas chromatography. The stated "method quantification limit" in the study was "0.400 µg/200 mL sample" (i.e., 0.001 µg/cm^2 of sample surface area based on an area of 400 cm^2). The recovery data from all facets of the study were acceptable. Method validation recoveries averaged 88.0% ± 2.5% (C.V. = 2.8). Concurrent laboratory recoveries were similar where the recoveries averaged 106.0% ± 16.8% (C.V. = 15.8). "Field" recovery samples results ranged from 79.1 to 106 percent recovery at both sites. At the California site, field recoveries averaged 97.2% ± 7.5% (C.V. = 7.7). At the Georgia site, field recoveries averaged 98.4% ± 6.1% (C.V. = 6.2). Stability during freezer storage has also been demonstrated in a separate study where stability was determined to be quantitative after approximately 90 days of storage. Given these quality control results, the Agency did not correct the resulting residue levels for recovery. At the California site, average residues on the day of application were 1.01 µg/cm^2 and were still detectable even 63 days after the application where the average residue was 0.00174 µg/cm^2 (i.e., approximately 0.2 % of the original residue level). At the Georgia site, average residues on the day of application were 1.36 µg/cm^2 and were still detectable out to 21 days after the application where the average residue was 0.00145 µg/cm^2 (i.e., approximately 0.1 % of the original residue level). The quicker dissipation rate in Georgia is not unanticipated by the Agency given the more humid conditions typically found in Georgia and considering the amount of rainfall that occurred during the study.

- **MRID 43505901:** The dissipation of vinclozolin dislodgeable foliar residues after airblast application of Ronilan DF at 1.0 lb ai/acre to peaches in Pennsylvania was quantified. Applications were made with an airblast sprayer using 50 gallons of water per acre. Dislodgeable foliar residue samples were collected using the standard approach with a Birkestrand leaf punch device and aqueous surfactant washing (i.e., the Iwata method). Duplicate samples were collected prior to and after the application then approximately 1, 2, 3, 7, 10, 14, 21, 28, 35, 42, 49, 56, and 63 days after application (i.e., 40 punches with a 1 inch diameter punch = 400 cm^2 per sample). Samples were dislodged and frozen on the day of collection. Field recovery samples were generated at each study site on 4 distinct sample collection days, on 2 days the solutions were prepared with hexane and on the other days the solutions were prepared with MTBE. Triplicate tank mix solution samples were also collected for each application. The application was completed on August 13, 1992. There was a total of 6.7 inches of rainfall and no irrigation over the course of the study. The first rainfall event occurred 1 day after application with 0.2 inches of precipitation (2.01 inches in the first 14 days). The collected aqueous samples were analyzed by extraction with hexane in a separatory funnel followed by quantification by gas chromatography. The stated "method quantification limit" in the study was "0.400 µg/200 mL sample" (i.e., 0.001 µg/cm^2 of sample surface area based on an area of 400 cm^2). The recovery data from all facets of the study were acceptable. Method validation recoveries averaged 92.5% ± 9.1% (C.V. = 9.8). Concurrent laboratory recoveries (1 obvious outlier excluded) were similar where the recoveries averaged 107.5% ± 13.1% (C.V. = 12.2). "Field" recovery samples results ranged from 80.3 to 106 percent and averaged 91.4% ± 9.7% (C.V. = 10.6). Stability during freezer storage has also been demonstrated in a separate study where stability was determined to be quantitative. Given these quality control results, the Agency did not correct the resulting residue levels for recovery. Average residues on the day of application were 1.45 µg/cm^2 and were still detectable even 56 days after the application where the average residue was near the method quantification limit of 0.001 µg/cm^2 (i.e., approximately 0.07 % of the original residue level).

- **MRID 42830002:** This study was completed in conjunction with MRID 42830001 in which the dissipation of vinclozolin dislodgeable foliar residues after airblast application of Ronilan DF at 1.0 lb ai/acre to peaches in California was quantified. A single application was made with an airblast sprayer using 50 gallons of water per acre on August 17, 1992. In this study, peach harvesting was monitored on the day of application and 7 days after application. Five individuals were monitored during harvesting activities over 4-three hour intervals thus providing a total of 20 exposure measurements (i.e., 20 replicates). Each individual was monitored for approximately 3 hours per replicate. For each individual, two replicates were completed on the day of application and the remaining two were completed 7 days after application. One replicate per individual was completed in the morning of each sampling day while the other was completed in the afternoon. Exposures were monitored using passive dosimetry techniques. Dermal exposures were monitored using whole body dosimetry (separate long-sleeved shirts and pants worn under normal work clothing), handwashes (600 mL of 0.01% aqueous Aerosol OT 75 solution), and facial/neck wipes. Inhalation exposures were monitored using personal sampling pumps and glass fiber filters. Normal work clothing was worn over these dosimeters. Urine samples were also collected but the results were not included in this report. A total of 3 field recovery samples for each media were generated on each day of sampling. Single samples of each media were fortified at three different levels (i.e., dosimeter and wipes range from 10 to 1000 µg per sample, handwashes range from 50 to 500 µg per sample, and filters range from 0.1 to 100 µg per sample). Air was pulled through the filter samples under actual field conditions. There was no recorded rainfall or foliar irrigation completed over the course of this study. All samples were extracted with hexane (i.e., reciprocal shaking or partitioning) and quantified using gas chromatography. The stated "method quantification limit" in the study was as follows for each monitoring media: whole-body dosimeters - 1.0 µg/sample; handwashes - 1.2 µg/sample; face/neck wipes - 1.0 µg/sample; and glass fiber filters - 0.025 µg/filter. Method validation recoveries averaged 114% ± 4.0% (C.V. = 3.5) for whole-body dosimeters, 91.6% ± 4.2% (C.V. = 4.5) for face/neck wipes, 118% ± 13.6% (C.V. = 11.5) for glass fiber filters, and 88% ± 2.5% (C.V. = 2.8) for handwashes. Concurrent laboratory recoveries were similar where the recoveries averaged 103% ± 10% (C.V. = 9.7) for whole-body dosimeters, 116% ± 4.4% (C.V. = 3.8) for face/neck wipes, 108% ± 22% (C.V. = 20.3) for glass fiber filters, and 111% ± 16% (C.V. = 14.4) for handwashes. Field recovery samples averaged 79.3% ± 27.3% (C.V. = 34.5) for whole-body dosimeters, 102.6% ± 5.9% (C.V. = 5.8) for face/neck wipes, 55.6% ± 11% (C.V. = 19.9) for glass fiber filters, and 91.6% ± 6.9% (C.V. = 7.6) for handwashes. The investigators indicated that all residue levels were corrected for field recovery results based on the "average of field fortification percent recoveries if <100%." On the day of application, the rate of dermal exposure for harvesting activities ranged from 0.91 to 2.02 mg/hour while exposures 7 days after application ranged from 0.036 to 0.145 mg/hour. Likewise, average exposure rates on the day of application were 1.25 ± 0.52 mg/hour (C.V. = 41.6) and were 0.089 ± 0.039 mg/hour (C.V. = 43.8) 7 days after application. Total dermal exposure for harvesting activities ranged from 2.7 to 6.1 mg on the day of application while exposures 7 days after application ranged from 0.11 to 0.44 mg. On the day of application, the rate of inhalation exposure (calculated using 45 Lpm human breathing rate by the investigators) for harvesting activities ranged from 0.07 to 0.14 mg/hour while exposures 7 days after application ranged from 0.002 to 0.007 mg/hour. Likewise, average exposure rates on the day of application were 0.104 ± 0.026 mg/hour (C.V. = 25) and were 0.004 ± 0.001 mg/hour (C.V. = 25) 7 days after application. The transfer coefficient calculated by the investigators in this report was 1321 cm^2/hour which was defined by calculating a value for each day of sampling using average exposure and DFR values and then averaging each daily value. This transfer coefficient represents exposures to individuals wearing normal work clothing as the monitored individuals wore long pants and long-sleeved shirts during the study.

<u>Monitoring Data For Strawberries:</u>

C **MRID 43013004:** The dissipation of vinclozolin dislodgeable foliar residues after six foliar applications of Ronilan DF at 1.0 lb ai/acre to strawberries at three different sites was quantified (Michigan and in the central valley as well as along the southern coast of California). Applications were made with a groundboom sprayer using 100 gallons of water per acre in each application. Dislodgeable foliar residue samples were collected using the standard approach with a Birkestrand leaf punch device and aqueous surfactant washing (i.e., the Iwata method). Duplicate samples were collected prior to and after the application then approximately 1, 2, 3, 7, 10, 14, 21, 28, 35, 42, 49, 56, and 63 days after application (i.e., 40 punches with a 1 inch diameter punch = 400 cm^2 per sample). Samples were dislodged and frozen on the day of collection. Field recovery samples were generated at each study site on 6 distinct sample collection days, on 4 days the solutions were prepared with hexane and on the other days the solutions were prepared with MTBE. Triplicate tank mix solution samples were also collected for each application. The six applications at the central valley site in California were initiated on 9/1/92 and concluded on 10/6/92 (all were done at 1 week intervals). DFR samples were collected before and after each application then out to 63 days after the final application. There was no recorded rainfall or foliar irrigation (furrow irrigation was routine) completed in the study after the last application until 10/21/92 when 0.19 inches of rain fell. The six applications at the southern coast site in California were initiated on 6/26/92 and concluded on 7/31/92 (all were done at 1 week intervals). DFR samples were collected before and after each application then out to 63 days after the final application. There was no recorded rainfall or foliar irrigation (furrow irrigation was routine) completed in the study after the last application until 8/14/92 when 0.15 inches of rain fell. The six applications at the Michigan site were initiated on 7/1/92 and concluded on 8/5/92 (all were done at 1 week intervals). DFR samples were collected before and after each application then out to 63 days after the final application. There was no recorded rainfall or foliar irrigation (furrow irrigation was routine) completed in the study after the last application until 8/8/92 when 0.7 inches of rain fell. The collected aqueous samples were analyzed by extraction with hexane in a separatory funnel followed by quantification by gas chromatography. The stated "method quantification limit" in the study was "0.400 µg/200 mL sample" (i.e., 0.001 µg/cm^2 of sample surface area based on an area of 400 cm^2). The recovery data from all facets of the study were acceptable. Method validation recoveries averaged 88.0% ± 2.5% (C.V. = 2.8). Concurrent laboratory recoveries were similar where the recoveries averaged 105.0% ± 23.7% (C.V. = 22.6). "Field" recovery samples results ranged from 69.5 to 135 percent recovery at all sites. At the central valley California site, field recoveries averaged 88.5% ± 7.7% (C.V. = 8.7). At the southern coast California site, field recoveries averaged 96.5% ± 11.7% (C.V. = 12.1). At the Michigan site, field recoveries averaged 88.8% ± 10.4% (C.V. = 11.7). Stability during freezer storage has also been demonstrated in a separate study where stability was determined to be quantitative stability during storage. Given these quality control results, the Agency did not correct the resulting residue levels for recovery (i.e., the overall field recovery value was 91.2% ± 10.6%, C.V. = 11.6). At the central valley site in California, residues did not appear to accumulate between each of the six applications. Average residues on the day of application were highest after the 3rd of 6 applications at a concentration of 2.48 µg/cm^2 and were at a concentration of 1.45 µg/cm^2 after the sixth (final) application. Residues were still detectable even 63 days after the application where the average residue was 0.00908 µg/cm^2 (i.e., approximately 0.6 % of the original residue level). At the southern coast site in California, residues did not appear to accumulate between each of the six applications. Average residues on the day of application were highest after the 2nd of 6 applications at a concentration of 2.19 µg/cm^2 and were at a concentration of 1.68 µg/cm^2 after the sixth (final) application. Residues were still detectable out to 35 days after the application where the average residue was 0.00318 µg/cm^2 (i.e., approximately 0.2 % of the original residue level). At the Michigan site, residues did not appear to accumulate between each of the six applications. Average residues on the day of application were highest after the last application where the concentration was 2.10 µg/cm^2. Residues were still detectable out to 56 days after the application where the average residue was 0.00143 µg/cm^2 (i.e., approximately 0.07 % of the original residue level).

- **MRID 43013005:** The dissipation of vinclozolin surface soil residues after six foliar applications of Ronilan DF at 1.0 lb ai/acre to strawberries at a site in the central valley of California (i.e., this study was conducted in conjunction with MRIDs 43013004 and 43013003). Applications were made with a groundboom sprayer using 100 gallons of water per acre in each application. Dislodgeable foliar residue samples were collected using the standard approach with a Birkestrand leaf punch device and aqueous surfactant washing (i.e., the Iwata method). Duplicate samples were collected prior to and after the application then approximately 1, 2, 3, 7, 10, 14, 21, 28, 35, 42, 49, and 56 days after application. Dust samples (i.e., approximately 50 grams each) were collected by "drawing the dust through a 100-mesh brass screen (450 cm2) with a portable vacuum." Samples were frozen on the day of collection. Field recovery samples were generated at each study site on 7 distinct sample collection days, on 4 days the solutions were prepared with hexane and on the other days the solutions were prepared with MTBE. Triplicate tank mix solution samples were also collected for each application. The six applications at the central valley site in California were initiated on 9/1/92 and concluded on 10/6/92 (all were done at 1 week intervals). There was no recorded rainfall or foliar irrigation (furrow irrigation was routine) completed in the study after the last application until 10/21/92 when 0.19 inches of rain fell. The collected aqueous samples were analyzed by extraction with methanol followed by clean-up procedures and quantification by gas chromatography. The stated "method quantification limit" in the study was 0.01 µg/g of sample (i.e., 0.01 ppm). The recovery data from all facets of the study were acceptable. Method validation recoveries averaged 86.4% ± 12.2% (C.V. = 14.1). Concurrent laboratory recoveries were similar where the recoveries averaged 104.0% ± 14.9% (C.V. = 14.3). Field recovery samples results ranged from 75.1 to 102 percent with an average recovery of 93.2% ± 7.5% (C.V. = 8.0). Given these quality control results, the Agency did not correct the resulting residue levels for recovery. Residues did not appear to appreciably accumulate between each of the six applications. Average residues (all reported are based on soil dry weight) on the day of application were highest after the 5th of 6 applications at a concentration of 26.1 ppm and were at a concentration of 19.1 ppm after the sixth (final) application. Residues were still detectable even 56 days after the application where the average residue was 0.231 ppm (i.e., approximately 1.2 % of the original residue level).

- **MRID 43013003:** This study was completed in conjunction with MRIDs 43013004 and 43013005 in which the dissipation of vinclozolin dislodgeable foliar and soil residues after six groundboom applications of Ronilan DF at 1.0 lb ai/acre to strawberries in California were quantified. The six applications at the southern coast site in California were initiated on 6/26/92 and concluded on 7/31/92 (all were done at 1 week intervals). In this study, strawberry harvesting was monitored on the day of application and 2 days after application. Five individuals were monitored during harvesting activities over 4-three hour intervals thus providing a total of 20 exposure measurements (i.e., 20 replicates). Each individual was monitored for approximately 3 hours per replicate. For each individual, two replicates were completed on the day of application and the remaining two were completed 2 days after application. One replicate per individual was completed in the morning of each sampling day while the other was completed in the afternoon. Exposures were monitored using passive dosimetry techniques. Dermal exposures were monitored using whole body dosimetry (separate long-sleeved shirts and pants worn under normal work clothing), handwashes (600 mL of 0.01% aqueous Aerosol OT 75 solution), and facial/neck wipes. Normal work clothing was worn over these dosimeters. Inhalation exposures were monitored using personal sampling pumps and glass fiber filters. A total of 3 field recovery samples for each media were generated on each day of sampling. Single samples of each media were fortified at three different levels (i.e., dosimeter and wipes range from 10 to 1000 µg per sample, handwashes range from 50 to 500 µg per sample, and filters range from 0.1 to 100 µg per sample). Air was pulled through the filter samples under actual field conditions. There was no recorded rainfall or foliar irrigation completed over the course of this study. All samples were extracted with hexane (i.e., reciprocal shaking or partitioning) and quantified using gas chromatography. The stated "method quantification limit" in the study was as follows for each monitoring media: whole-body dosimeters - 1.0 µg/sample; handwashes - 1.2 µg/sample; face/neck wipes - 1.0 µg/sample; and glass fiber filters - 0.025 µg/filter. Method validation recoveries were similar to the peach harvester study described above. Concurrent laboratory recoveries were similar where the recoveries averaged 108% ± 19.6% (C.V. = 18.1) for whole-body dosimeters, 106% ± 9.6% (C.V. = 9.1) for face/neck wipes, 99.4% ± 12.8% (C.V. = 12.8) for glass fiber filters, and 96.0% ± 15.1% (C.V. = 15.7) for handwashes. Field recovery samples averaged 74.9% ± 21.2% (C.V. = 28.3) for whole-body dosimeters, 98.1% ± 2.2% (C.V. = 2.2) for face/neck wipes, 65.1% ± 14.2% (C.V. = 21.8) for glass fiber filters, and 73.5% ± 15.7% (C.V. = 21.4) for handwashes. The investigators indicated that all residue levels were corrected for field recovery results. On the day of application, the rate of dermal exposure for harvesting activities ranged from 1.11 to 1.97 mg/hour while exposures 2 days after application ranged from 0.521 to 1.08 mg/hour. Likewise, average exposure rates on the day of application were 1.43 ± 0.29 mg/hour (C.V. = 20.3) and were 0.746 ± 0.179 mg/hour (C.V. = 24.0) 2 days after application. Total dermal exposure for harvesting activities ranged from 3.3 to 5.9 mg on the day of application while exposures 2 days after application ranged from 1.6 to 3.2 mg. On the day of application, the rate of inhalation exposure (calculated using 29 Lpm human breathing rate by the investigators) for harvesting activities ranged from 0.0047 to 0.017 mg/hour while exposures 2 days after application ranged from 0.0052 to 0.0098 mg/hour. Likewise, average exposure rates on the day of application were 0.0096 ± 0.0038 mg/hour (C.V. = 40) and were 0.0069 ± 0.0017 mg/hour (C.V. = 25) 2 days after application. The transfer coefficient calculated by the investigators in this report was 686 cm^2/hour which was defined by calculating a value for each day of sampling using average exposure and DFR values and then averaging each daily value together. This transfer coefficient represents exposures to individuals wearing normal work clothing as the monitored individuals wore long pants and long-sleeved shirts during the study.

Monitoring Data For Turf:

C **MRID 43343701:** The dissipation of vinclozolin turf transferable residues (TTRs) after four sequential groundboom applications of Ronilan DF, at an application rate of 5.6 lb ai/acre, were quantified at sites in California (fescue/rye mix) and Pennsylvania (bluegrass). Applications were made on 14 day intervals. TTRs were quantified using two distinct measurement techniques at each site including the use of aqueous dislodging solutions with turf clippings (analogous to the Iwata DFR method) and the California roller method that uses a cotton cloth sampling media. Applications were made with a groundboom sprayer using 80 gallons of water per acre. Duplicate samples were collected prior to and after the application then approximately 1, 2, 3, 7, 10, 14, 21, 28, 35, 42, 49, 56, and 63 days after application. All samples were dislodged and/or frozen on the day of collection. Field recovery samples were generated at each study site on 8 distinct sample collection days, on 6 days the solutions were prepared with hexane and on the other days the solutions were prepared with MTBE. Triplicate tank mix solution samples were also collected for each application. Applications at the California site were initiated on June 30, 1992 and were completed on August 11, 1992. There was substantial irrigation completed in the study between applications (e.g., over 20 inches between applications 3 and 4). There was no irrigation after the last application until at least 4 days after application where 5.4 inches of irrigation water were applied to the test site. The plot was also mowed between applications and just prior to the last application. Applications at the Pennsylvania site were initiated on June 18, 1992 and were completed on July 30, 1992. There was substantial rainfall noted in the study between applications, in fact 0.01 and 0.015 inches of rainfall were noted on the day of and 2 days after the final application. There was no irrigation apparently completed at the study site. The plot was also mowed between applications and just prior to the last application. The collected aqueous samples were analyzed by extraction with hexane in a separatory funnel followed by quantification by gas chromatography. The stated "method quantification limit" in the study was 0.600 µg/300 mL sample (i.e., clipping a 1600 cm^2 area and collecting a 10 g subsample for dislodging -- samples are normalized on this surface area and not that of grass clipped) for the aqueous dislodgeable samples and 0.001 µg/cm^2 (i.e., 1 µg/sample and a 927 cm^2 sample surface area). The recovery data from all facets of the study were acceptable. Method validation recoveries averaged 92.5% ± 9.13% (C.V. = 9.9) for the dislodging solutions and 96.4% ± 8.15% (C.V. = 8.5) for the cotton roller material. Concurrent laboratory recoveries were similar where the recoveries averaged 105.0% ± 23.8% (C.V. = 22.7) for the dislodging solutions and 102.0% ± 9.54% (C.V. = 9.4) for the cotton roller material. Field recovery samples results ranged from 66.1 to 165 percent recovery for the dislodging solutions and from 62.0 to 99.4 percent recovery for the California cloth rollers at both sites. At the California site, field recoveries averaged 102% ± 19.5% (C.V. = 19.1) for the dislodging solutions and 91.6% ± 6.11% (C.V. = 6.7) for the California cloth roller material. At the Pennsylvania site, field recoveries averaged 90.5% ± 7.86% (C.V. = 8.7) for the dislodging solutions and 76.6% ± 12.4% (C.V. = 16.2) for the California cloth roller material. Stability during freezer storage has also been demonstrated in a separate study where stability was determined to be quantitative. Given these quality control results, the investigators appeared to correct the results for field recovery as appropriate. At the California site, residues did not seem to accumulate between applications based on the results using either sampling method. Average residues measured using the aqueous solution method in California after applications ranged from 7.09 µg/cm^2 to 15.3 µg/cm^2 with a value of 10.6 µg/cm^2 after the final application. Residues were still detectable even 63 days after the final application where the average residue was 0.0012 µg/cm^2 (i.e., approximately 0.01 % of the original residue level). Average residues measured using the California cloth roller method at the California site after applications ranged from 0.802 µg/cm^2 to 1.24 µg/cm^2 after the final application. Residues were still detectable even 56 days after the final application where the average residue was 0.0015µg/cm^2 (i.e., approximately 0.1 % of the original residue level). The rapid decline in residues at the California site is expected based on the amount of irrigation water applied to the site and because of mowing. At the Pennsylvania site, residues did not seem to appreciably accumulate between applications based on the results using either sampling method. Average residues measured using the aqueous solution method in Pennsylvania after applications ranged from 9.13 $\mu g/cm^2$ to 24.5 $\mu g/cm^2$ after the final application. Residues were still detectable even 63 days after the final application where the average residue was 0.00438 $\mu g/cm^2$ (i.e., approximately 0.02 % of the original residue level). Average residues measured using the California cloth roller method at the Pennsylvania site after applications ranged from 0.198 $\mu g/cm^2$ to 0.725 $\mu g/cm^2$ after the final application. Residues were still detectable even 28 days after the final application where the average residue was 0.0011$\mu g/cm^2$ (i.e., approximately 0.2 % of the original residue level). The rapid decline in residues at the California site was expected based on the amount of irrigation water applied to the site and because of mowing and at the Pennsylvania site because of rainfall and mowing.

C **MRID 43528701:** The dissipation of vinclozolin turf transferable residues (TTRs) after four sequential groundboom applications of Ronilan DF, at an application rate of 5.6 lb ai/acre, were quantified at a site in Florida on bermudagrass. Applications were made on 14 day intervals. TTRs were quantified using two distinct measurement techniques at each site including the use of aqueous dislodging solutions with turf clippings (analogous to the Iwata DFR method) and the California roller method that uses a cotton cloth sampling media. Applications were made with a groundboom sprayer using 80 gallons of water per acre. Duplicate samples were collected prior to and after the application then approximately 1, 2, 3, 7, 10, 14, 21, 28, 35, 42, 49, 56, and 63 days after application. All samples were dislodged and/or frozen on the day of collection. Field recovery samples were generated at each study site on 7 distinct sample collection days, on 6 days the solutions were prepared with hexane and on the other days the solutions were prepared with MTBE. Triplicate tank mix solution samples were also collected for each application. Applications at the site were initiated on July 22, 1992 and were completed on September 2, 1992. There was substantial irrigation completed in the study between applications (e.g., about 15 inches between applications). There was no irrigation after the last application but rainfall was noted on 6 of the 7 days immediately following the final application (i.e., a total of 1.69 inches of water). The plot was also mowed between applications and just prior to the last application. The collected aqueous samples were analyzed by extraction with hexane in a separatory funnel followed by quantification by gas chromatography. The stated “method quantification limit” in the study was 0.600 µg/300 mL sample (i.e., clipping a 1600 cm^2 area and collecting a 10 g subsample for dislodging -- samples are normalized on this surface area and not that of grass clipped) for the aqueous dislodgeable samples and 0.001 $\mu g/cm^2$ (i.e., 1 µg/sample and a 927 cm^2 sample surface area). The recovery data from all facets of the study were acceptable. Method validation recoveries averaged 92.5% ± 9.13% (C.V. = 9.9) for the dislodging solutions and 96.4% ± 8.15% (C.V. = 8.5) for the cotton roller material. Concurrent laboratory recoveries were similar where the recoveries averaged 100.2% ± 11.8% (C.V. = 11.8) for the dislodging solutions and 105.9% ± 22.0% (C.V. = 20.8) for the cotton roller material. Field recovery samples results ranged from to percent recovery for the dislodging solutions and from to percent recovery for the California cloth rollers. Field recoveries averaged 92.5% ± 9.9% (C.V. = 10.7) for the dislodging solutions and 74.2% ± 9.54% (C.V. = 12.9) for the

California cloth roller material. Given these quality control results, the investigators appeared to correct the results for field recovery as appropriate. Residues did not seem to accumulate between applications based on the results using either sampling method. Average residues measured using the aqueous solution method after applications ranged from 3.75 $\mu g/cm^2$ to 6.09 $\mu g/cm^2$ with a value of 3.75 $\mu g/cm^2$ after the final application. Residues were still detectable even 28 days after the final application where the average residue was 0.00198 $\mu g/cm^2$ (i.e., approximately 0.05 % of the original residue level). Average residues measured using the California cloth roller method at the California site after applications ranged from 0.375 $\mu g/cm^2$ to 1.07 $\mu g/cm^2$ with a value of 0.645$\mu g/cm^2$ after the final application. Residues were still detectable 7 days after the final application where the average residue was 0.00121$\mu g/cm^2$ (i.e., approximately 0.3 % of the original residue level). The rapid decline in residues is expected based on the amount of rainfall at the site and because of mowing.

- **MRID 43343702:** This study was completed in conjunction with MRID 43343701 in which the dissipation of vinclozolin turf transferable residues after four groundboom applications of Ronilan DF at 5.6 lb ai/acre to turf (a fescue/rye mixture) in California were quantified. The four applications were initiated on June 30, 1992 and were completed on August 11, 1992. There was substantial irrigation completed in the study between applications (e.g., over 20 inches between applications 3 and 4). There was no irrigation after the last application until at least 4 days after application where 5.4 inches of irrigation water were applied to the test site. The plot was also mowed between applications and just prior to the last application. In this study, dermal exposures on turf using the Jazzercize protocol were monitored on the day of the final application. A total of 10 individuals were monitored twice, the first set of replicates were completed "after the sprays had dried" while the second series of replicates were completed approximately 1 hour after the first set for a total of 20 replicates, all on the day of application. Each individual was monitored for approximately 20 minutes per replicate which is the amount of time generally required for the Jazzercize routine (i.e., routine sets R4-87, R3-88, R3-48, and R1-89). Exposures were monitored using passive dosimetry techniques. Dermal exposures were monitored using whole body dosimetry (separate socks, cotton gloves, long-sleeved shirts, and pants worn with no outer clothing), handwashes (300 mL of 0.01% aqueous Aerosol OT 75 solution), and facial/neck wipes. Inhalation exposures were monitored using personal sampling pumps and glass fiber filters that were not worn by the monitored individuals but that were placed at a fixed location near the center of the treated plot. The inhalation monitors were placed at 2 distinct heights from the treated turf, 6 and 36 inches in height. A total of 3 field recovery samples for each media were generated on each day of sampling. Single samples of each media were fortified at three different levels (i.e., dosimeter, wipes, handwash, and filters range from 10 to 1000 µg per sample, sock and gloves range from 1 to 100 µg per sample). Air was pulled through the filter samples under actual field conditions. There was no recorded rainfall or foliar irrigation completed over the course of this study. All samples were extracted with hexane (i.e., reciprocal shaking or partitioning) and quantified using gas chromatography. The stated "method quantification limit" in the study was as follows for each monitoring media: whole-body dosimeters - 1.0 µg/sample; handwashes - 0.6 µg/sample; face/neck wipes - 1.0 µg/sample; socks - 10.0 µg/sample, and glass fiber filters - 0.025 µg/filter. Method validation recoveries are summarized for each media. These recoveries averaged 92.5 ± 9.13% (C.V. = 9.9) for handwash solutions, 109 ± 11.4% (C.V. =

10.5) for gloves, 97.4 ± 12.1% (C.V. = 12.4) for socks, 118 ± 13.6% (C.V. = 11.5) for inhalation filters, 105 ± 12.4% (C.V. = 11.8) for whole-body dosimeters, and 91.6 ± 4.16% (C.V. = 4.5) for swipes. Concurrent laboratory recoveries were similar where the recoveries averaged 104 ± 9.9% (C.V. = 9.5) for handwash solutions, 121 ± 37.9% (C.V. = 31.3) for gloves, 110 ± 7.47% (C.V. = 6.8) for socks, 95.7 ± 13.3% (C.V. = 13.9) for inhalation filters, 97.5 ± 21.9% (C.V. = 22.5) for whole-body dosimeters, and 115 ± 26.5% (C.V. = 23.0) for swipes. Field recovery samples averaged 89.6 ± 16.9% (C.V. = 18.9) for handwash solutions, 113.7 ± 17.0% (C.V. = 15.0) for gloves, 102.5 ± 0.71% (C.V. = 0.7) for socks, 100 ± 18.3% (C.V. = 18.3) for inhalation filters, 107.6 ± 13.7% (C.V. = 12.7) for whole-body dosimeters, and 96.0 ± 10.6% (C.V. = 11.1) for swipes. The investigators indicated that all residue levels were corrected, as appropriate, for field recovery results. The rate of dermal exposure for the Jazzercize activities ranged from 51.4 to 123 mg/hour while the average exposure rates were 90.6 ± 20.2 mg/hour (C.V. = 22.3). Likewise, total dermal exposures ranged from 13.7 to 32.7 mg/replicate. The rate of inhalation exposure (calculated using 25 Lpm human breathing rate by the investigators) for harvesting activities ranged from 0.0212 to 0.146 mg/hour at the 6 inch height level and 0.00384 to 0.00548 mg/hour at the 36 inch level. Transfer coefficients are calculated by defining the ratio of exposure to a transferable residue concentration. Transfer coefficients for the same activity can differ based on how the transferable residue concentration value is determined. In the corresponding TTR study, two different methodologies were used to collect TTR data including the aqueous leafwash approach and the California cloth roller. The investigators in this report calculated transfer coefficients for the Jazzercize activity using both sets of TTR data. If the California cloth roller method data is used, the transfer coefficient is 75,327 cm^2/hour. If the aqueous leafwash method data is used, the transfer coefficient is 8,812 cm^2/hour. The Agency has been careful to apply each transfer coefficient only to the corresponding TTR data in this assessment.

As with the handler risk assessment presented above, both noncancer and cancer risks were calculated in this assessment. The calculations used to estimate *Daily Dermal Dose*, noncancer *MOE*s, and cancer risks (both MOEs and population risk estimates using the Q_1*) for the post-application scenarios are similar to those described above for the handler scenarios. The only significant differences are (1) the manner in which the *Daily Dermal Dose* is calculated using a transfer coefficient, chemical-specific exposure and dislodgeable foliar/turf transferable residue levels, and accounting for the dissipation of vinclozolin over time; (2) inhalation exposures were not calculated for the postapplication scenarios (i.e., *Total Daily Dose* in the MOE calculation only represents dose levels resulting from dermal exposures because the data do reflect inhalation exposures which have been shown, historically, to account for a negligible percentage of the overall body burden); and (3) non-dietary ingestion exposures were calculated for subpopulations where the behavior can be anticipated with relative certainty along with a calculation of associated dose from dermal exposure (i.e., toddlers after contact with treated turf).

The first step in the post-application risk assessment was to complete an analysis of the available dislodgeable foliar residue (DFR) and turf transferable residue (TTR) dissipation data. All residue data generated in the studies referenced above are presented in Appendices D, E, and F of this document. The data for peaches are included in Appendix D while Appendices E and F contain the data for strawberries and turf, respectively. These data were used to complete the postapplication risk assessment for all occupational scenarios and for the exposure scenarios resulting from the use of vinclozolin on turf. Generally, DFR and TTR samples are not collected on each day after application over a period of time that would be of sufficient duration for the calculation of Restricted Entry Intervals (REIs) and other post-application risk assessments. Therefore, the Agency uses these types of dissipation data to develop a series of predicted concentrations, based on the empirical data, to calculate exposures and risks on separate days after application to define the REI or other post-application risks.

The Agency typically uses an exponential, pseudo-first order kinetics model to calculate DFR and TTR concentration levels for a period of time after application generally determined by the duration of sampling, decay pattern, and method quantification limits. This method also is based on the use of actual Day 0 concentration data in the calculation. Equation D2-16 from *Series 875-Occupational and Residential Test Guidelines: Group B-Postapplication Exposure Monitoring Test Guidelines* (U.S. EPA, 1997) is the basis for this analysis and is shown below:

$$C_{envir(t)} = C_{envir(0)} e^{PAI_{(t)} * M}$$

Where:
$\mathbf{C_{envir(t)}}$ = dislodgeable foliar residue or turf transferable residue concentration (µg/cm^2) that represents the amount of residue on the surface of a contacted leaf surface that is available for dermal exposure at time (t);
$\mathbf{C_{envir(o)}}$ = dislodgeable foliar residue or turf transferable residue concentration (µg/cm^2) that represents the amount of residue on the surface of a contacted leaf surface that is available for dermal exposure at time (0);
e = inverse of natural logarithms base function;
$\mathbf{PAI_t}$ = postapplication interval or dissipation time (e.g., days after treatment or DAT); and
M = slope of line generated during linear regression of data [ln(C_{envir}) versus postapplication interval (PAI)].

The slope (M) of the line for the dissipation data is defined for the above equation by completing a regression analysis for a simple line using semi-log transformed dissipation data (i.e., [ln(C_{envir}) versus postapplication interval (PAI)]). Equation D2-17 from *Series 875-Occupational and Residential Test Guidelines: Group B-Postapplication Exposure Monitoring Test Guidelines* (U.S. EPA, 1997) is the basis for this analysis and is shown below:

$$\ln(C_{envir(t)}) = (M * PAI_{(t)}) + b$$

Where:
$\mathbf{C_{envir(t)}}$ = dislodgeable foliar residue or turf transferable residue concentration (µg/cm^2) that represents the amount of residue on the surface of a contacted leaf surface that is available for dermal exposure at time (t);
b = y intercept of line generated during linear regression of data [ln(C_{envir}) versus postapplication interval (PAI)];
ln = natural logarithms base function;
$\mathbf{PAI_t}$ = postapplication interval or dissipation time (e.g., days after treatment or DAT); and

M = slope of line generated during linear regression of data [ln(C_{envir}) versus postapplication interval (PAI)]**.**

The simple linear regression model (Eqn. D2-17) has also been used by the Agency, registrants, and other investigators as the basis for an approach to predicting DFR or TTR residue levels over time in lieu of the exponential decay model (Eqn. D2-16). It should be noted, however, that the current Agency approach is to use the exponential decay model for predicting DFR or TTR concentrations over time if the data are sufficiently linear which appears to be the case for vinclozolin.

Even given the guidance provided in the Series 875 guideline document described above, there is still opportunity for interpretation of the approaches described therein including how the raw data should be manipulated and/or transformed prior to using the described kinetics models. How the data are handled can clearly alter the results of assessments. In July of 1997, components of the then current working *Draft Reregistration Eligibility Document for Vinclozolin* were provided to the registrant, BASF corporation. This included a series of analysis of the chemical- and scenario-specific DFR, TTR, and human exposure monitoring data and the accompanying exposure/risk calculations. In response to this document, BASF in October of 1997, provided a another interpretation of the data by providing a reanalysis of the draft RED regression analyses suggesting that some of the approaches presented in the draft RED were inappropriate (i.e., MRIDs 444094-01, 444094-02, and 444094-03). The primary difference between the BASF analysis and the Agency's analysis was that the sample data were generally truncated 10 days or so after application where the Agency had used more of the complete dataset. The Agency has extensively explored the implications of the comments and changes suggested by the registrant in the development of this current RED document. As such, the data have been analyzed by the Agency using 5 distinct approaches (i.e., current and historical Agency approaches as well as BASF proposed approaches) to illustrate the differences inherent in each method. [Note: The data were not corrected for recovery in any calculation by the Agency and it appears that the data were corrected by the investigators as appropriate depending upon field recovery results. The same datapoints were used by the Agency in the development of this risk assessment as were used in various risk assessments by the BASF Corporation.] The 5 different methods used in this document for analysis of the residue dissipation data are described below:

- **Dissipation Method 1:** This method was used by BASF. Generally, data up to postapplication day 10 were used in the regression analysis. Replicates were averaged and data were ln-transformed before the best fit analysis was completed. For each crop considered, regressions were conducted for each of the sites in the study as well as for the mean DFRs or TTRs from the three sites.

- **Dissipation Method 2:** This method was used in the draft 1997 Agency RED. Actual data for all sample collection days were used in the analysis with some exceptions where residues measured 1 day after application exceeded the values measured on the day of application. In these analyses, replicates were averaged and regressions were completed using ln-transformed data. For each crop considered, regressions were conducted for each of the sites in the study. The overall DFR or TTR values were calculated by averaging together the predicted (i.e., best-fit) DFRs calculated using the data from each site.

- **Dissipation Method 3:** This method is similar to that used in the draft 1997 Agency RED except that all of the raw data were used in the assessments (i.e., there were no adjustments made for high residue levels after the day of application as in Method 2).

- **Dissipation Method 4:** Actual data for all sample collection days were used in this analysis. In this approach, the DFR or TTR data for all sites per crop, on all sampling days where there were detectable residues were averaged together before conducting the regression analysis. The mean data were then ln-transformed for the regression.

- **Dissipation Method 5:** This analysis combined all individual data points for each specific crop and treated each replicate sample as a separate datapoint in the analysis. All days on which there were detected residues were used for the analysis. The entire dataset was ln-transformed for regression analysis.

The predicted values that were calculated using analysis method 4 were used as the basis for the risk assessment because they reflected the regional variability of the data (i.e., data from each site per crop were added together prior to the regression analysis) and the correlation coefficients calculated using this approach indicated acceptable linearity (i.e., applicability) for the model used. In *Section C: Occupational and Residential Risk Assessment Summary and Characterization* of this document, further discussion along with recommendations regarding appropriate use of these analyses for risk management purposes. See summary below:

Crop	Kinetics Analysis Method	Application Rate (lb ai/A)	Correlation Coefficient	Slope	Observed C_0 ($\mu g/cm^2$)	Half-Life (days)
Peaches	1	1	0.948	-0.265	1.274	2.6
	2		0.959	-0.195		3.6
	3		0.965	-0.206		3.4
	4		0.934	-0.108		6.4
	5		0.867	-0.121		5.7
Strawberries	1	1	0.967	-0.159	1.743	4.4
	2		0.936	-0.149		4.6
	3		0.969	-0.201		3.5
	4		0.932	-0.078		8.9
	5		0.742	-0.0964		7.2

Crop	Kinetics Analysis Method	Application Rate (lb ai/A)	Correlation Coefficient	Slope	Observed C_0 (µg/cm^2)	Half-Life (days)
Turf (Aqueous Wash Data)	1	5.6	0.934	-0.191	12.93	3.6
	2		0.992	-0.245		2.8
	3		0.989	-0.237		2.9
	4		0.994	-0.128		5.4
	5		0.851	-0.124		5.6
Turf (CA Roller Data)	1		0.941	-0.336	0.869	2.1
	2		NA	NA		NA
	3		0.959	-0.470		2.3
	4		0.963	-0.201		3.5
	5		0.803	-0.200		3.5

Notes:

- Data from each site combined and used for risk assessment purposes in all cases because of (1) the extrapolation that has been completed to different crops other than those used for the studies and (2) vinclozolin can be used in a variety of regions within the country -- considering data from different areas accounts for regional variability.
- The TTR data have been adjusted for risk assessment purposes based on differences in application rate (i.e., turf study conducted at 5.6 lb ai/acre and current label maximum is 1.35 lb ai/acre).
- As described in this document above, an exponential decay model is the current Agency standard for calculating predicting residue levels over time as described in equation D2-16 as presented in the Series 875, Group B guidelines (U.S. EPA, 1997).
- Half-life values calculated using equation D2-18 from the Series 875, Group B guidelines (U.S. EPA, 1997) which is a pseudo-first order kinetics model (i.e., $t_{1/2}$ = -0.693/M).
- In cases where the data from each of three sites are combined after the regression analysis has been completed (e.g., method 2), the average value over all three study sites has been presented. The California cloth roller turf dissipation data were not analyzed using method 2 as this was the original method that would not be selected for this analysis (i.e., to save resources).

In cases where no chemical-specific residue dissipation data are available, the Agency typically uses a generic dissipation model to complete risk calculations. In this case, the Agency has determined that it is more appropriate, however, to extrapolate using vinclozolin-specific dissipation data in risk assessments for other currently labeled crops than it is to use the generic dissipation model. This approach is consistent with current Agency policies. For vinclozolin, no chemical-specific residue dissipation data were available for any currently labeled crop/application target except for turf. The existing vinclozolin transferable residue data were extrapolated to the currently labeled crops as follows:

- **Peach Data:** The peach data were used to assess agricultural exposure scenario 4 which involves contact with tree fruit because of the similarities between application method (i.e., peaches and kiwi, for example, are both anticipated to be treated with an airblast sprayer that uses high speed air to obtain adequate crop canopy coverage).

C **Strawberry Data:** All other agricultural and ornamental scenarios are anticipated to treated with a groundboom sprayer or some other type of device that does not involve the high speed air assist found in applications using airblast equipment. Therefore, the strawberry DFR data have been used to complete the assessment for all other crops and ornamentals (including greenhouse exposure scenarios and excluding turf uses).

C **Turf Data:** For all turf-based post-application exposure scenarios the turf transferable residue dissipation data referenced above were used in all risk assessments.

Data from all peach, turf, and strawberry study sites have been used in the assessment as the crops for which vinclozolin is labeled can be and are grown across the country with a few notable exceptions (e.g., the kiwi assessment is only based on data from Florida and California). No adjustments to the peach or strawberry data have been completed based on application rate for the currently labeled crops as the maximum application rate for several crops is 1.0 lb ai/acre and the studies used in the assessment were based on sequential applications at that application rate. The turf transferable residue data were, however, adjusted for application rate because the current maximum application rate is 1.35 lb ai/acre and the turf dissipation data were generated after sequential applications at the then current maximum application rate of 5.6 lb ai/acre. Therefore, the turf dissipation data from the study were adjusted by multiplying the data by a factor of 0.24 (i.e., 1.35 lb ai/acre divided by 5.6 lb ai/acre).

The next step in the risk assessment process was to calculate dermal exposure values (remembering that inhalation exposures were not quantitatively assessed for these scenarios) on each post-application day after application using the following equation (see equation D2-20 from *Series 875-Occupational and Residential Test Guidelines: Group B-Postapplication Exposure Monitoring Test Guidelines*):

$$DE_{(t)}\ (\text{mg/day}) = (\ TTR_{(t)} \text{ or } DFR_{(t)}\ (\mu g/cm^2) \times TC\ (cm^2/hr) \times Hr/Day)/1000\ (\mu g/mg))$$

Where:

DE	=	Dermal exposure at time (t) attributable for activity in a previously treated area (mg/day);
DFR	=	Dislodgeable Foliar Residue at time (t) where the longest duration (t) is dictated by the kinetics observed in the DFR studies;
TTR	=	Turf Transferable Residue at time (t) where the longest duration (t) is dictated by the kinetics observed in the TTR studies;
TC	=	Transfer Coefficient (cm^2/hour); and
Hr	=	Exposure duration (hours).

As indicated above, the dislodgeable foliar or turf transferable residues represent the amount of chemical on the surfaces of treated leaves that can rub off on one's skin. The transfer coefficient is a value that represents the exposure one receives while performing a specific task or activity in an area previously treated with a pesticide. Exposure duration values represent the amount of time that individuals are expected to spend engaged in a job task or activity.

In addition to the available chemical-specific DFR or TTR data, transfer coefficients and duration of exposure are also key elements in the calculation of post-application exposures. The duration for the occupational assessments was 8 hours per day such as used by the Agency with all occupational settings in agriculture and for ornamentals with the exception of golf course maintenance activities where it is likely that an exposure duration of 4 hours would be more realistic. The residential assessment for children is based on a duration of 2 hours per day as described in the Agency's *SOPs For Residential Exposure Assessment* (see discussion of exposure factors below). The residential golfer exposure is based on a duration of 1 hour which is the anticipated amount of time that a golfer approximately spends on greens and tees during an 18-hole round of golf.

The transfer coefficients for all occupational scenarios are presented below and are based on the use of a baseline clothing scenario (long pants and a long-sleeved shirt). The transfer coefficients used for residential turf scenarios are also presented below and represent shorts and a short-sleeved shirt for golfers and minimal clothing (e.g., a diaper or shorts only) for toddlers on treated turf. The vinclozolin-specific transfer coefficients calculated by the Agency using chemical-specific data range from less than 500 to approximately 1800 for strawberry harvesting and from less than 1000 up to approximately 7500 for peach harvesting depending upon how they were calculated. Because these transfer coefficients are similar to and support the Agency standard values for similar activities but do not exactly match the activities considered in this assessment, the Agency standard transfer coefficient values were used as the basis for this assessment. Data were, however, used from a study conducted on turf that measured both turf transferable residues and human exposure while engaged in Jazzercize as opposed to the standard value used by the Agency for dermal exposures. The activities that were selected as the basis for the risk assessment are represented by the following transfer coefficients :

- **Transfer Coefficient = 10000 cm^2/hour used for Occupational Agricultural Scenario 4 and Occupational Ornamental Scenario 4:** for adults involved in a high exposure activity such as harvesting onions, kiwi, and trellised snapbeans, harvesting or placing sod, and cutting flowers in a greenhouse (i.e., represents standard Agency value for these activities);

- **Transfer Coefficient = 5000 cm^2/hour also used for Occupational Ornamental Scenario 4:** for adults involved cutting flowers in a greenhouse (i.e., represents scenario-specific transfer coefficient for work in a greenhouse, based on Brouwer et al, 1992 -- calculations are provided using this value in order to provide for a more informed risk management decision);

- **Transfer Coefficient = 4000 cm^2/hour used for Occupational Agricultural Scenario 3 and Occupational Ornamental Scenario 3:** for adults involved in a medium contact/exposure activity such as scouting raspberries and snapbeans, harvesting raspberries and low growing snapbeans, or irrigating ornamentals;

- **Transfer Coefficient = 2500 cm^2/hour used for Occupational Agricultural Scenario 2 and Occupational Ornamental Scenario 2:** for adults involved in a lower contact/exposure activity such as harvesting lettuce or sorting and packing ornamentals in a greenhouse;

- **Transfer Coefficient = 1000 cm^2/hour used for Occupational Agricultural Scenario 1:** for adults involved in a lower contact/exposure activity such as scouting in canola, onions, lettuce, and other low row crops;

- **Transfer Coefficient = 500 cm^2/hour used for Occupational Ornamental Scenario 1 and Residential Scenario 1:** for adults involved in a lower contact/exposure activity such as golfing on treated courses or mowing/maintaining treated turf;

- **Transfer Coefficient = 1062 cm^2/hour based on leaf wash residue data or 9082 cm^2/hour based on California cloth roller data, used in Residential Scenario 2:** for toddlers involved in a high exposure activity on treated turf represented by the Jazzercize protocol, the registrants reported transfer coefficients of 8,812 cm^2/hour and 75,327 cm^2/hour. The registrant calculated these values by defining the ratio of exposure rate (µg/hour) to the turf transferable residue concentration (µg/cm^2). These transfer coefficients for the adult test subjects were adjusted by two factors including (1) the surface area differences between adults and 3 year olds (i.e., a factor of approximately 2.76 lower for toddlers) and (2) the theory that each 20 minutes of Jazzercize is equivalent to 1 hours worth of children's activities on turf as presented by the Agency at the October 1999 FIFRA Science Advisory Panel meeting. [Note: For the calculation of dermal risks related to the turf use pattern, the cloth roller based TTR concentration data are used. The leaf wash data have been used to complete the nondietary ingestion risk assessment as this technique is likely a better measure for transferability when calculating oral exposures.]

The post-application exposure assessments do not include any dietary or drinking water inputs. They also do not include any dose attributable to nondietary ingestion (e.g., hand-to-mouth activity) because no toxicological endpoint was selected with which to assess short-/intermediate-term oral exposures (i.e., the only durations for which non-dietary exposures are thought to be plausible for vinclozolin).

Daily dose (i.e., a biologically appropriate and available dose resulting from dermal exposure) was then calculated by normalizing the daily exposure value by body weight and accounting for absorption. For adults, a body weight of 60 kg was used for all noncancer exposure scenarios because the toxic effect (decreased prostate weights in male offspring) is from a prenatal developmental toxicity study (i.e., it is sex-specific). For the cancer calculations, a body weight of 70 kg was used as this value reflects the general population (i.e., it is not sex-specific). Additionally, dermal absorption factor of 25.2 percent and an inhalation absorption factor of 100 percent were used for all calculations. Daily dose was calculated using the following formula:

$$\text{Daily Dose}\left(\frac{mg\ ai}{kg/day}\right) = \text{Daily Exposure}\left(\frac{mg\ ai}{day}\right) \times \left(\frac{\text{Absorption Factor}(\%/100)}{\text{Body Weight}\ (kg)}\right)$$

Where:

Daily Dose = the amount as potential dose (for the short- and intermediate-term dermal calculations) or absorbed dose (for cancer, or nondietary ingestion calculations) received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day);
Daily Exposure = the amount of dermal (on the skin) or nondietary ingestion (from mouthing behaviors of

children) exposure calculated above (mg pesticide active ingredient/day);
Absorption Factor = a measure of the flux or amount of chemical that crosses a biological boundary (% of the total available); and
Body Weight = body weight determined to represent the population of interest in a risk assessment (kg).

[Note: The U.S. EPA Exposure Assessment Guidelines (EPA, 1992) define potential dose as the amount of a chemical at the absorption barrier. Additionally, absorbed dose is defined as the amount of a chemical that has been absorbed and is available for interaction with biologically significant receptors.]

Risks in this assessment were calculated using two different approaches based on the toxicological effect being evaluated. Risks attributable to noncancer effects were calculated in a non-probabilistic manner using the Margin of Exposure (MOE) which is a ratio of the calculated exposure to the appropriate toxic endpoint of concern. For most exposures (which are anticipated to be less than 6 months) MOEs were calculated by comparing exposures to the endpoint defined from a prenatal developmental toxicity study in rats (i.e., decreased prostate weights with a NOAEL of 3 mg/kg/day). For exposures longer than 180 days, MOEs were calculated by using an endpoint from a chronic rat toxicity study (i.e., several effects noted with a NOAEL of 1.2 mg/kg/day). [Note: See Section 2.b.i for more details about the specific endpoints used in each assessment.] MOEs were calculated using the formula below:

$$MOE = \frac{Endpoint\ (NOAEL)\left(\frac{mg}{kg/day}\right)}{Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

Where:

MOE = margin of exposure or value used by the Agency to represent noncancer risk or how close a chemical exposure is to being a concern (unitless);
Daily Dose = the absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day); and
Endpoint (LOAEL, NOAEL) = dose level in a toxicity study where no observed adverse effects occurred in the study (mg pesticide active ingredient/kg body weight/day).

A margin of exposure (MOE) uncertainty factor of 100 is considered an appropriate risk level for all occupational exposures to vinclozolin regardless of the duration. This factor was determined based on the standard Agency approach of accounting for inter-species variability and intra-species sensitivity.

In addition to the noncancer assessments that have been completed for vinclozolin, the Agency also has concerns over the development of cancer from exposure to vinclozolin. Two types of these calculations were completed. The first type was based on a threshold approach using

MOEs as the measure of cancer risk. The cancer MOEs were calculated as described above for the noncancer effects with the appropriate toxicological endpoint. The other type of cancer risk calculation using the linear low-dose extrapolation first requires the calculation of a LADD (Lifetime Average Daily Dose) using the following equation:

$$LADD_{abs} = Daily\ Dose_{abs} * (Frequency/365) * (Exposure\ Duration/Lifetime\ Duration)$$

Where:

$LADD_{abs}$ = Internal or absorbed daily dose amortized over an individual's lifetime (mg pesticide active ingredient/kg body weight/day);
$Daily\ Dose_{abs}$ = the amount of absorbed dose received from exposure to a pesticide in a given scenario, as calculated above for MOE analysis -- only internal or absorbed dose is appropriate for cancer calculations (mg pesticide active ingredient/kg body weight/day);
Frequency = the number of days exposed to a pesticide of concern per annum (days/year);
Exposure Duration = the number of years throughout a lifetime that a person is exposed to a specific chemical (years); and
Lifetime Duration = anticipated lifetime of an individual in the exposure population of interest (years).

[Note: The U.S. EPA Exposure Assessment Guidelines (EPA, 1992) define absorbed dose as the amount of a chemical that has been absorbed and is available for interaction with biologically significant receptors.]

Once LADD values were calculated for each scenario of concern, cancer risks were calculated using the Q_1* value for vinclozolin of 2.9×10^{-1} $(mg/kg/day)^{-1}$. Generally, the use of a Q_1* approach is based on the premise that there is no dose threshold in the carcinogenic mechanism and any dose received can be related to a cancer risk in a linear fashion (i.e., referred to as linear low dose extrapolation). However, the available cancer mechanism data for vinclozolin indicate that linear extrapolation of dose is only applicable after extended periods of exposure. Therefore, the Agency has completed a cancer risk assessment only for exposures that meet this criteria. Cancer risks represent the probability of excess cancer cases in a population over a lifetime. Cancer risks have been calculated by the Agency using the following equation:

$$Risk = LADD_{int} * (Q_1^*)$$

Where:

Risk = the probability of deleterious health effects as described in the U.S. EPA Exposure Assessment Guidelines of May 1992 (unitless);
$LADD_{abs}$ = Internal daily dose amortized over an individual's lifetime as calculated above (mg pesticide active ingredient/kg body weight/day); and
Q_1* = measure of cancer potency $(mg/kg/day)^{-1}$.

It should be noted that the Agency does not typically complete cancer risk assessments for children as the policies for these kinds of assessments are currently under development on an Agency-wide basis.

The *Food Quality Protection Act (FQPA)* requires that the Agency aggregate (or add together) exposures that can occur in a variety of different ways to a chemical. The assessments described above, that were focused only on dermal exposures, are meant to address the exposures of adults during occupational activities and adults engaged in residential activities such as golfing. In these scenarios, dermal exposure is predominant so no other type of exposure was considered. [Note: Occupational exposures are not subject to the requirements of FQPA for aggregation of exposures.] However, the assessment for determining harvest intervals for turf from sodfarms differs because the Agency considered the exposures of children which include both dermal exposures and those exposures attributable to their mouthing behaviors. Routine mouthing behaviors are thought to lead to additional exposures which must be considered along with their dermal exposure. In all assessments of this type, the Agency considers a suite of exposures that can occur because of mouthing behaviors including hand-to-mouth, object-to-mouth, and soil ingestion events (i.e., referred to as non-dietary exposures). The Agency uses the *SOPs For Residential Exposure Assessments* and the recently proposed revisions to this document (i.e., October, 1999 FIFRA Science Advisory Panel Meeting) as guidance for completing residential risk assessments of this type. Specifically, the kinds of nondietary exposures that were considered in this assessment include the following:

C ***Dose from hand to mouth activity calculated using SOP 2.3.2:*** Postapplication dose among toddlers from incidental nondietary ingestion of pesticide residues on treated turf from hand-to-mouth transfer (i.e., those residues that end up in the mouth from a child touching turf and then putting their hands in their mouth);

C ***Dose from object to mouth activity calculated using SOP 2.3.3:*** Postapplication dose among toddlers from incidental nondietary ingestion of pesticide residues on treated turf from object-to-mouth transfer (i.e., those residues that end up in the mouth from a child mouthing a handful of treated turf); and

C ***Dose from soil ingestion activity calculated using SOP 2.3.4:*** Postapplication dose among toddlers from incidental nondietary ingestion of pesticide residues from ingesting soil in a treated turf area (i.e., those soil residues that end up in the mouth from a child touching treated soil and turf then putting their hands in their mouth).

Three equations are presented below that illustrate how the Agency calculated exposure levels using the concept of transferable residues and soil concentration data. Transferable residues represent the amount of chemical on treated surfaces that can rub off on one's skin. The dermal or nondietary ingestion exposure levels calculated using these equations were then also used to calculate dose levels, MOEs, and cancer risks as illustrated above. The following illustrates the approach used to calculate the nondietary ingestion exposures that are attributable to contact with a treated turf (SOP 2.3.2):

$$D = (TTR * (SE/100) * SA * Freq * Hr * (1mg/1000\mu g))$$

where:

D	=	dose from hand-to-mouth activity (mg/day);
TTR	=	Turf Transferable Residue at time (t) where the longest duration (t) is dictated by the kinetics observed in the TTR study (µg/cm^2);
SE	=	saliva extraction factor (%);
SA	=	surface area of the hands (cm^2);
Freq	=	frequency of hand-to-mouth events (events/hour); and
Hr	=	exposure duration (hours).

As indicated above, the turf transferable residue represents the amount of chemical on the surfaces of treated leaves that can rub off on one's skin. The data from the BASF, TTR study referenced above (leaf wash method for nondietary ingestion dose calculations) are used in this risk assessment.

The following illustrates the basics of the approach, used to calculate exposures that are attributable to a child mouthing treated turf (SOP 2.3.3):

$$D = (TTR * (SE/100) * IgR * (1mg/1000\mu g))$$

where:

D	=	dose from mouthing activity (mg/day);
SE	=	saliva extraction factor (%);
TTR	=	Turf Transferable Residue (TTR) at time (t) where the longest duration (t) is dictated by the kinetics observed in the TTR study (µg/cm^2); and
IgR	=	ingestion rate for mouthing of grass per day (cm^2/day).

The following illustrates the basics of the approach, used to calculate exposures that are attributable to soil ingestion (SOP 2.3.4):

$$D = (SR * IgR * (1E{-}6\ g/1\ \mu g))$$

where:

D	=	dose from soil ingestion activity (mg/day);
SR	=	Soil Residue at time (t) where the longest duration (t) is dictated by the kinetics observed in the accompanying TTR study (µg/cm^2); and
IgR	=	ingestion rate for daily soil ingestion (mg/day).

It should be noted that the Agency does not typically complete cancer risk assessments for children as the policies for these kinds of assessments are currently under development on an Agency-wide basis.

The data upon which the postapplication risk assessment is based are presented in Appendices D (peach data), E (strawberry data), and F (turf data). These Appendices contain the dissipation data, the results of each of the kinetics analysis approaches for each dataset, the exposure data for each activity monitored, and the calculation of the transfer coefficient for each activity. Appendix G contains the results of the occupational aspects of the post-application risk assessment for all agricultural and ornamental uses considered. Appendix H contains the results of the residential aspects of the post-application risk assessment.

The following specific assumptions and factors were used in order to complete this exposure assessment:

- These assessments were based on the guidance provided, as appropriate, in the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines (7/24/97 Version)* and the *Draft: Standard Operating Procedures (SOPs) for Residential Exposure Assessment (12/11/97 Version)*. Several of the assumptions and factors used in the exposure assessment are described in that document. The Agency brought several issues related to the *SOPs For Residential Exposure Assessment* before the FIFRA Science Advisory Panel in September of 1999. The revisions to the current document proposed by the Agency at that meeting have been incorporated into this assessment.

- For the short-/intermediate-term non-cancer risk assessments, the average body weight of an adult handler is 60 kg because the NOAELs used for the short- and intermediate-term assessments were selected based on developmental concerns for female populations (ages 13+). This body weight value represents that of adult females in the general population. For the chronic noncancer assessments and the cancer risk assessments, the average body weight of an adult handler is 70 kg because the biological mechanism that leads to the chronic toxicity or the development of cancer is not sex-specific. This body weight value represents that of adults, both male and female, in the general population.

- The Agency believes that the vast majority of exposures occur in short- and intermediate-term durations of exposure (i.e., up to 6 months of continuous exposure with most exposures being a month or less in duration). However, for complete stewardship and for a more informed risk management decision, the Agency has also completed a chronic exposure assessment (i.e., for scenarios with greater than 180 days of continuous exposure) for selected exposure scenarios where it is believed that exposures of these durations could occur. The Agency does not believe that chronic exposures occur in agriculture. Chronic exposures are, however, believed to occur for some uses in the ornamental industry. For example, it is likely in the production of cut flowers such as roses an individual could be involved in harvesting and maintenance activities that could be chronic in nature. Short-/Intermediate-term non-cancer risks (i.e., MOEs) have been calculated for all exposure scenarios and only for specific scenarios for which the Agency believes chronic exposures occur. If the Agency does not believe that a chronic duration assessment is needed for specific scenarios, then no value will have been calculated and included in the tables in Appendices G and H.

- The turf calculations are based on data that were generated at a maximum application rate of 5.6 lb ai/acre. The current application rates for turf have been reduced to 1.35 lb ai/acre. The data, where appropriate, have been adjusted by the Agency using a simple proportion to reflect this change in application rates.

- A cancer risk assessment using both a threshold (MOE) approach and linear low-dose extrapolation is required for vinclozolin because the available cancer mechanism data indicate that this method is appropriate only for exposures of extended duration. The appropriate absorbed dose to be used in these assessments is the LADD (Lifetime Average Daily Dose) in which exposures over an individual's lifetime are amortized. In order to calculate LADD values for vinclozolin exposures, the Agency has used the following inputs for exposure frequency (number of events per year), average length of lifetime, and number of years involved in an activity. In all assessments a lifetime duration value of 70 years has been used per Agency policy along with the working life duration of 35 years. Frequency values are also required for risk assessment purposes appropriate to each type of application method and crop/target evaluated. These frequency values are intended to represent the average annual frequency of application events (i.e., exposures) on an annual basis. In this case, since cancers are a concern only for individuals who are exposed over an extended duration, the frequency values used for all assessments (i.e., 90 and 180 days) represent exposures for a very small segment of the vinclozolin user population and are not intended to reflect typical use patterns as is the case with most cancer risk assessments. The Agency has completed the cancer risk assessment only for a selected small segment of the population where the exposure patterns fit criteria of extended periods of exposure as defined by the available mechanism data. If the Agency does not believe that a chronic duration assessment is needed for specific scenarios, then no value will have been calculated and included in the tables in Appendices G and H.

- The use of administrative controls (i.e., establishing an REI) are not considered acceptable options for products sold for use in areas where the general population can be exposed such as golf courses. The risk assessment for the sodfarm use of vinclozolin is unique in that a time interval has been established that defines the amount of time vinclozolin residues are required to dissipate prior to harvesting sod (with a buffer of 1 day to account for harvest, transport, and placement in a residential environment) in order to preclude vinclozolin residues at levels that demonstrate a risk concern from entering the residential environment where infants and children can be exposed.

- The exposure duration used in the assessment for most occupationally exposed populations is 8 hours. However, a 4 hour duration value has been used to complete the calculations for golf course turf maintenance. For the residential postapplication exposure scenarios, several durations were considered in the development of this risk assessment including 2 hours per day for children engaged in active play activities on turf. The golfer exposure duration value used in this assessment is 4 hours which represents the approximate amount of time required to complete an 18 hole round of golf.

- For the occupational risk assessment, single day exposures were calculated to reflect chemical-specific residue dissipation rates over time coupled with surrogate transfer coefficients ranging from 500 to 10,000 cm^2/hour in order to address the range of exposures anticipated with vinclozolin. It is likely that an occupationally exposed population could be subjected to areas where repetitive applications have occurred thus requiring HED to assess each scenario using identical daily dose levels over extended periods of time (i.e., intermediate-term dose levels are not amortized). In the residential risk assessment for golfers and children on treated turf, the Agency has calculated single day exposures to reflect chemical-specific residue dissipation rates over time coupled with a chemical-specific transfer coefficients of 500 cm^2/hour for golfing and either 1,062 or 9,082 cm^2/hour depending upon which turf transferable residue dataset is used.

- For the nondietary ingestion dose calculations resulting from hand-to-mouth behaviors, the surface area for hands used (40 cm^2) which represents the palmar surface area of three fingers for a toddler (age 3 years). Based on available videography data, this appears to be grossly representative of the typical area placed in the mouth during these behaviors. The time spent outdoors (2 hours/day) is referenced directly from the *SOPs For Residential Exposure Assessment.* The 2 hour duration value is also a recommended value from the *U.S. EPA Exposure Factors Handbook* (U.S. EPA, 1997). The saliva extraction value (i.e., this factor could also be called removal efficiency) used in the calculation is 50 percent as proposed by the Agency at the October 1999 FIFRA Science Advisory Panel (SAP) Meeting. It should be noted that the measurement technique used to generate the TTR concentrations used in this assessment is thought to roughly approximate or even exceed the removal efficiency of saliva thereby adding some conservatism to the assessment. The frequency of events considered in this calculation (20 events per hour) was proposed as a modification to the current Agency Residential SOPs at the October 1999 FIFRA SAP meeting.

- The turf transferable residue data used in this risk assessment were generated in the study using two distinct measurement techniques including an aqueous surfactant method and the California cloth roller method. The data generated using the California cloth roller have been used to calculate postapplication dermal exposures after contact with treated turf because the Jazzercize transfer coefficient used in the assessment was calculated using these data and this method is generally recognized by the scientific community as the most appropriate TTR measurement method for this purpose. This can also be illustrated by the selection of this method by the Outdoor Residential Exposure Task Force as the technique of choice for quantifying TTRs (i.e., BASF is a member of this task force). For all nondietary ingestion exposures, the TTRs generated using the aqueous wash method were used as the basis for the risk assessment because these values are thought to be more representative of childrens' hand contact with treated surfaces (e.g., childrens hands might be wet).

- For the nondietary ingestion dose calculations resulting from object-to-mouth behaviors, the surface area of the object ingested (25 cm^2) which represents the surface area that is thought to approximate a handful of turf that is mouthed during an exposure interval.

- For the nondietary ingestion dose calculations resulting from soil ingestion, the amount of soil ingested (100 mg) is referenced directly from the *SOPs For Residential Exposure Assessment* and is also a recommended value from the *U.S. EPA Exposure Factors Handbook* (U.S. EPA, 1997). The soil concentrations used in this assessment were calculated based on the application rate, using the dissipation pattern from the TTR data, and by assuming that residues are distributed in the top centimeter of soil as described in the *SOPs For Residential Exposure Assessment*. A density factor for soil of 0.67 cm^3/gram was also used which again is referenced in the *SOPs For Residential Exposure Assessment*.

c. Occupational and Residential Risk Assessment Summary and Characterization

The risk assessment completed in Section 2.b is summarized herein. Please refer to the tables presented in Appendices A through H if required as they are the basis for this risk assessment. This section of the document presents the results of the risk assessment and the factors that should be considered when interpreting the results.

i. General Risk Characterization Considerations

This risk assessment was completed using the data developed in the studies presented above. The Agency has also received several risk assessments from the registrant of vinclozolin, the BASF corporation. The Agency has not formally reviewed these risk assessments. However, the Agency has considered the factors used in the risk assessment submitted by BASF so that consistency between the current Agency assessment and the submitted documents can be evaluated. The submitted risk assessments can be identified by the following:

- MRID 44409401 Baugher, D. (1997) Vinclozolin: Reevaluation of Reentry Exposure and Margins of Exposure in Strawberries, OAI Project Number, 42097V: 97016/VIN, Unpublished study prepared by Orius Associates Inc. 67 p.

- MRID 44409402 Baugher, D. (1997) Vinclozolin: Reevaluation of Reentry Exposure and Margins of Exposure in Peaches, OAI Project Number, 42097V: 97019/VIN, Unpublished study prepared by Orius Associates Inc. 26 p.

- MRID 44409403 Baugher, D. (1997) Vinclozolin: Reevaluation of Reentry Exposure and Margins of Exposure in Golf Course Turf, OAI Project Number, 42097V: 97017/VIN, Unpublished study prepared by Orius Associates Inc. 24 p.

- MRID 44409404 Baugher, D. (1997) Vinclozolin: Reevaluation of Mixer/Loader and Applicator Exposure and Margins of Exposure: Lab Project Number, 42097V: 97018/VIN: 97/5375. Unpublished study prepared by Orius Associates Inc. 11 p.

- MRID 43983502 Baugher, D. (1996) Vinclozolin 50 DF: Exposure and Margins of Exposure for Snap Bean Irrigation Workers, Mixer/Loaders, and Applicators: Lab Project Number: 96/5033:

40696: 96010/VIN. Unpublished study prepared by Orius Associates, Inc. 19 p.

- MRID 43013006 Baugher, D. (1993) *Dislodgeable Foliar Residues, Surface Soil Residues, Harvester Exposure, and Margin of Safety Assessments For Reentry Into Strawberries Treated With Ronilan (Vinclozolin) 50DF Fungicide* Sponsor: BASF 2520 Meridian Parkway, P.O. Box 13528, Durham N.C.; Conducting Facility: Orius Associates Inc. 615 North Market Street, Frederick Maryland; OAI Report No. 37993.

- MRID 42830003 Baugher, D. (1993) Dislodgeable Foliar Residues, Exposure, and Margin of Safety Assessments for Harvester Reentry into Peaches Treated with Ronilan (Vinclozolin) 50 DF Fungicide: Lab Project Number: 37993: 63-VIN/93005: 93/5060. Unpublished study prepared by Orius Associates Inc. 16 p.

- MRID 42483102 Baugher, D. (1992) Exposure and Margin of Safety Assessments For Mixer/Loaders and Applicators Using Ronilan (Vinclozolin) 50 WP and DF Fungicide, Sponsor: BASF P.O. Box 13528, RTP N.C.; Conducting Facility: Orius Associates Inc. 615 North Market Street, Frederick Maryland; Reg. Doc. No. 92/5111

- MRID 44006101 Baugher, D. (1996) *Dermal Exposure of Mixer/Loaders Using Ronilan (Vinclozolin) DF Contact Fungicide: Aerial Application to Canola in Canada, 1995* Sponsor: BASF Canada, Inc., 345 Carlingview Drive, Toronto Ontario; Conducting Facility: Orius Associates Inc. 660 Orchard Lane, Aspers Pennsylvania; BASF Study No. 95092, OAI Report No. 39995.

The major issues and differences between the assessments completed by BASF and the risk assessments completed by the Agency include:

- MRIDs 444094-01 through 444094-04 are the latest risk assessments completed and submitted to the Agency by BASF for vinclozolin. In the strawberry assessment, a Monte Carlo approach was used. The Agency is developing guidance for reviewing these types of assessments and hence has not reviewed the results. In some cases, a NOEL of 12 versus 3 mg/kg/day was used as the basis for the risk assessment when the current NOAEL as identified by the Agency's HIARC committee is 3 mg/kg/day. Biological monitoring data generated in a referenced handler study on canola (conducted in Canada) were not used in the assessment. Peach and strawberry uses have been deleted from the current labeling so these assessments are no longer directly applicable for this document. Finally, the dermal exposure level proposed for turf exposures (e.g., golfers and mowers) is not consistent with Agency policies. This assessment is based on current policies. The registrant in each of these postapplication assessments completed a kinetics analysis using the data that is slightly different than the Agency completed in the draft RED document of 1997. The Agency considered these alternative kinetics approaches in this assessment.

- The snapbean risk assessment completed in MRID 439835-02 indicates that hand harvesting should not be considered because harvesting is mostly mechanical and it is theorized that irrigation pipe placement is a higher exposure activity than harvesting. Average daily dose levels (handler and postapplication) were also calculated by amortizing exposures over a year to define annualized daily dose levels - the Agency does not use this approach for calculating intermediate-term exposures. The registrant also believed that a lower acreage treated value for handler risk assessment purposes is appropriate (i.e., 25 acres per day versus the standard Agency approach of 80 acres per day).

C Several of the risk assessments that were considered in the development of this document were earlier iterations of risk assessments for peach harvesters, strawberry harvesters, and handlers (i.e., MRIDs 428300-03,430130-06, 424831-02, and 440061-01). As such, these documents were not considered in the development of this document as it is anticipated that these documents do not represent current BASF positions with regard to vinclozolin as each of these risk assessments were updated/upgraded in 1997.

Several issues must be considered that pertain to the quality of the assessment and when interpreting the results of the occupational handler and residential postapplication risk assessment. These include:

C Two chemical-specific handler exposure studies were submitted for vinclozolin. These data have previously been incorporated into the Pesticide Handlers Exposure Database (V1.1) that is currently available to the public. As such, as is Agency policy, these data as well as the remaining data from PHED (i.e., they were combined) were used as the basis for the exposure/risk assessment. These studies also included a biological monitoring component that is based on a different level of personal protection than the passive dosimetry numbers (i.e., because dosimeters themselves account for an additional level of personal protection). The biological monitoring data from both studies are considered inconclusive for quantitative risk assessment purposes because of a lack of reliable pharmacokinetic information and because of the differences in levels of personal protection. The general trends in the passive dosimetry data and biological monitoring data, however, were consistent with one another. The unit exposures that were calculated using PHED for just the individual studies were obviously consistent with the unit exposure levels calculated for each scenario of concern as the overall unit exposures for each affected exposures were based in part on the data for vinclozolin. The data from both vinclozolin studies are presented in Appendices B and C. The unit exposures used in the calculation of handler risks (i.e., that reflect the overall PHED dataset) are presented in Appendix A/Table 2.

C Surrogate dermal transfer coefficients were used to assess occupational postapplication exposures even though vinclozolin-specific transfer coefficients were available for peach and strawberry harvesting. Peaches and strawberries have been removed from current vinclozolin labeling and it is believed that these activities and the circumstances of the studies are distinct enough to not justify using them to quantitatively complete an assessment for other types of exposures. As such, standard Agency values for occupational exposures in agriculture and for uses on ornamentals were used as the basis for this assessment (i.e., from 500 to 10,000 cm^2/hour). The vinclozolin-specific transfer coefficient values generated for peach and strawberry harvesting fall within this range of transfer coefficients selected to complete the assessment. The residential aspects of the risk assessment were completed using the transfer coefficients from the vinclozolin Jazzercize dermal exposure study (i.e., two were calculated because two techniques were used to define turf transferable residue levels).

These transfer coefficients were used in lieu of the standard Jazzercize-based dermal transfer coefficient that is specified in the Agency's *SOPs For Residential Exposure Assessment*. The value that has been used to assess golfer risks is a standard Agency value as there is no vinclozolin-specific postapplication exposure data for golfers.

- Several generic protection factors were used to calculate handler exposures. The protection factors used for clothing layers and gloves have not been completely evaluated by the Agency. There is an ongoing project through NAFTA to address the issue of protection factors (a draft document assessing protection factors using PHED has been completed). The key element being evaluated by the Agency are the factors for clothing and gloves. The value used for respiratory protection is based on the *NIOSH Respirator Decision Logic*. It should also be noted that the value used for gloves is in the range that OSHA and NIOSH often use.

- Exposure factors (e.g., acres treated and application rates) used to calculate daily exposures to handlers are based on applicable data if available. Otherwise, values are based on the best professional judgement of Agency assessors due to a lack of pertinent data and assumptions such as the number of acres treated per day or the number of gallons spray solution prepared and applied for handheld equipment types. The recent draft NAFTA exposure factor summary (e.g., acres/day/equipment type) was also consulted. These factors are believed to represent reasonable to conservative estimates for calculating exposures.

- Turf transferable residues measured at three different sites were used to complete the assessments for sodfarm turf harvesting. The dislodgeable foliar residue data from peaches and strawberries were used to complete all other postapplication assessments. The peach data were used for the tree fruit assessments (i.e., kiwi is only currently labeled crop). All other postapplication risk assessments were completed using the strawberry data. These data were used in this manner because of the differences in application method between the two types of data. The strawberry data were generated after application with a groundboom sprayer, which is the expected application method for many of the currently labeled crops or it is similar to other application methods as groundboom equipment in that it does not have the additional air assist as is found with airblast equipment which was used in the peach studies. The Agency acknowledges that there are other issues associated with using peach and strawberry data to extrapolate to other crops where vinclozolin can be used, especially for ornamentals, such as leaf type and growing conditions associated with each crop. The Agency, however, believes that the use of these data is a more appropriate measure of dissipation than the use of the generic Agency dissipation model (i.e., 5 or 20 % initial transferability followed by a 10 % decline per day) that would have been used as an alternative.

- The Agency normally completes both short- and intermediate-term occupational risk assessments for noncancer endpoints. For vinclozolin, a chronic-term risk assessment was also completed for a selected group of exposure scenarios that are believed to occur in this pattern, namely handler and postapplication uses in the floriculture industry.

- A cancer risk assessment was completed for vinclozolin. In this case, cancer risks were calculated using a linear low-dose extrapolation approach (i.e., a Q_1*) and a threshold (i.e., MOE approach). This approach was taken by the Agency because the Q_1* approach can be used for regulatory decision making as the Agency has developed policies for addressing cancer risks of certain levels based on this approach. The use of the MOE approach is supported by the cancer mechanism data. Based on the cancer mechanism data, the Agency believes that only exposures over an extended period will lead to the development of cancer. As such, the number of exposure scenarios considered in the cancer risk assessment included in this document is limited. For each of these scenarios, a duration of exposure of 90 or 180 days, which is analogous to the available cancer mechanism data, has been used to complete the assessment using the Q_1* approach. The MOE approach has been completed using the same daily exposure values that have been calculated for the short-/intermediate-term and chronic noncancer assessments.

- Job functions are not combined for some scenarios where field logistics might dictate that a single person would complete all aspects of the application process (e.g., mixer/loaders and groundboom or airblast applications). In these cases, the Agency has calculated values for each aspect of the job in order to have more flexibility in the development of risk mitigation strategies (e.g., separately for wettable powder mixer/loaders and for groundboom applicators even though an individual may complete all job tasks). In these cases, it would be favorable to compare risks for individuals completing separate jobs versus those for individuals involved in more than one task. This has not been done, however, as the data required for an effective comparison are not available (e.g., in PHED).

- The Agency considered groups of crops/use sites, application rates, and activities in this assessment. It is not possible to address every potential exposure pattern (i.e., by rate and crop) because of a lack of data to support the inputs and because of the complexity that would be added to the risk assessment. For example, categories of generic transfer coefficients were used to complete the postapplication exposure assessments as no scenario-specific postapplication exposure data were available to complete the assessment. With the development of more refined data, the Agency will complete risk assessments for more activities.

- The Agency always considers the maximum application rates allowed by labels in its risk assessments in order to be able to consider what is legally possible based on the label in order to ensure proper stewardship. If more information is available concerning the use patterns of the chemical, the Agency tries to incorporate it into the risk assessment process. Average application rates were available from a recent analysis. The results of this analysis indicate that in most cases, average application rates differ from maximum application rates on average by a factor of two or less. The Agency used these rates in the assessment. However, the impact on the calculated risks is small because there is little difference between the average and maximum application rates.

- The exposure duration (i.e., years per lifetime) values used by the Agency in this assessment are in compliance with current Agency policies for cancer risk assessment.

- Application scenarios for golf courses have not been considered as a separate series of exposure scenarios in this assessment. Rather, the exposures and risks associated with this use pattern are accounted for by the scenarios generically considered for applications to turf. For example, the risks associated with the use of a high pressure handwand or low pressure/high volume turfgun would also represent the risks associated with the golf course use pattern.

- Application scenarios for greenhouse uses have not been considered as a separate series of exposure scenarios in this assessment except for some specialized uses such as cut flower dipping. Rather, the exposures and risks associated with this use pattern are accounted for by the scenarios generically considered for applications using various handheld application methods such as the high pressure handwand or low pressure/high volume turfgun.

Refinement of the ORE exposure and risk assessment calculations presented in this chapter is possible if the issues presented above are addressed by the registrant or if more refined approaches and data become available to the Agency.

ii. Occupational Handler Risk Summary

In this assessment, risks for handlers were assessed using toxicological endpoints derived from oral administration toxicity studies for both dermal and inhalation exposures in the short-/intermediate-term and also for chronic exposures. The resulting risks (MOE values) were then added in order to obtain an overall risk for each applicator that accounted for both dermal and inhalation exposures for each exposure duration considered. Additionally, a cancer risk assessment was completed using the LADD/Q_1* approach and the MOE or threshold approach . Dermal and inhalation risks are mitigated using different types of protective equipment so it may be acceptable to add a pair of gloves and not a respirator or vice versa. All of the risk calculations for occupational handlers completed in this assessment are included in Appendix A (i.e., there are no residential use products for vinclozolin, so no homeowner handler scenarios were assessed). The specifics of each of table included in Appendix A are described below as well as a summary of the risks for each exposure scenario.

- **Table 1: Sources of Exposure Data Used in the Occupational Vinclozolin Handler Exposure and Risk Calculations** Describes the sources of the exposure data used in all of the occupational handler calculations.

- **Table 2: Input Parameters For Vinclozolin Occupational Handler Exposure and Risk Calculations** Presents the exposure values and other exposure factors used in the occupational handler noncancer and cancer risk assessments.

- **Table 3: Vinclozolin Occupational Handler Exposure and Risk Calculations At The Baseline Protection Level** Presents the short-/intermediate-term, chronic, and cancer MOEs for vinclozolin at the baseline level of personal protection. The baseline level of personal protection represents typical work clothing or a long-sleeved shirt and long pants with no respiratory protection. No chemical-resistant gloves are included in this scenario. Therefore, some scenarios have no baseline dermal exposure assessments (see notes on Table 2). [Note: The calculations from this table have been used to develop the summary in Tables 7 through 11.]

- **Table 4: Vinclozolin Occupational Handler Exposure and Risk Calculations At The Minimum PPE Protection Levels** Presents the short-/intermediate-term, chronic, and cancer MOEs for vinclozolin at the minimum level of personal protection. The minimum PPE level of personal protection represents the baseline scenario with the use of chemical-resistant gloves and PF 5 respirators. [Note: The calculations from this table have been used to develop the summary in Tables 7 through 11.]

- **Table 5: Vinclozolin Occupational Handler Exposure and Risk Calculations At The Maximum PPE Protection Levels** Presents the short-/intermediate-term, chronic, and cancer MOEs for vinclozolin at the maximum level of personal protection. The maximum level of personal protection represents the baseline scenario with the use of an additional layer of clothing (e.g., a pair of coveralls), chemical-resistant gloves, and, in some cases, a PF 10 respirator. [Note: The calculations from this table have been used to develop the summary in Tables 7 through 11.]

- **Table 6: Vinclozolin Occupational Handler Exposure and Risk Calculations At The Engineering Control Protection Levels** Presents the short-/intermediate-term, chronic, and cancer MOEs for vinclozolin when using engineering controls as personal protection. Engineering controls represent the use of systems such as a closed tractor cab or closed loading system for granulars or liquids. Engineering controls are not applicable to handheld application methods there are no known devices that can be used to routinely lower the exposures for these methods. [Note: The calculations from this table have been used to develop the summary in Tables 7 through 11.]

- **Table 7: Vinclozolin MOEs Attributable to Occupational Dermal Exposure** Summarizes all MOEs calculated for dermal exposures at each level of personal protection (i.e., baseline through engineering controls). [Note: See tables 3 through 6 for calculations of specific MOE values.]

- **Table 8: Vinclozolin MOEs Attributable to Occupational Inhalation Exposure** Summarizes all MOEs calculated for inhalation exposures at each level of personal protection (i.e., baseline through engineering controls). [Note: See tables 3 through 6 for calculations of specific MOE values.]

C **Table 9: Vinclozolin MOEs Attributable to Combined Short-/Intermediate-Term Dermal and Inhalation Exposures** Presents combined dermal and inhalation noncancer MOEs for short-/intermediate-term exposures with each possible combination of dermal and respiratory protection considered in this assessment. [Note: See tables 3 through 6 for calculations of specific MOE values.]

C **Table 10: Vinclozolin MOEs Attributable to Combined Chronic Dermal and Inhalation Exposures** Presents combined dermal and inhalation noncancer MOEs for chronic exposures with each possible combination of dermal and respiratory protection considered in this assessment. [Note: See tables 3 through 6 for calculations of specific MOE values.]

C **Table 11: Vinclozolin Cancer MOEs Attributable to Combined Dermal and Inhalation Exposures** Presents combined dermal and inhalation cancer MOEs with each possible combination of dermal and respiratory protection considered in this assessment. [Note: See tables 3 through 6 for calculations of specific MOE values.]

C **Table 12: Absorbed Average Daily Dose Levels (ADDs) Used In Calculation Of Cancer Risks For Vinclozolin Attributable To Combined Dermal And Inhalation Exposures** Presents the ADD values calculated for each possible combination of dermal and respiratory protection considered in this assessment. The ADDs have been calculated by adding the absorbed dermal and inhalation dose levels presented in tables 3 through 6.

C **Table 13: Absorbed Lifetime Average Daily Dose Levels (LADDs) Used In Calculation Of Cancer Risks For Vinclozolin Attributable To Combined Dermal And Inhalation Exposures (90 Annual Exposure Days)** Presents the LADD values calculated for each possible combination of dermal and respiratory protection considered in this assessment for individuals exposed over a 90 day period. The LADDs have been calculated by adding the absorbed dermal and inhalation dose levels presented in tables 3 through 6 and amortizing the values over a 70 year lifetime in which an individual is exposed to vinclozolin 90 times per year (depending upon the job) over a 35 year working duration. [Note: The Agency does not anticipate that this is a common exposure scenario and as such has completed these calculations for only a selected few exposure scenarios in floriculture where exposures of this duration are anticipated.]

C **Table 14: Occupational Cancer Risks Attributable To Combined Dermal And Inhalation Exposures (90 annual exposure days)** Presents the cancer risks for individuals who are exposed to vinclozolin over an extended duration of exposure (i.e., 90 days).

C **Table 15: Absorbed Lifetime Average Daily Dose Levels (LADDs) Used In Calculation Of Cancer Risks For Vinclozolin Attributable To Combined Dermal And Inhalation Exposures (180 Annual Exposure Days)** Presents the LADD values calculated for each possible combination of dermal and respiratory protection considered in this assessment for individuals exposed over a 180 day period. The LADDs have been calculated by adding the absorbed dermal and inhalation dose levels presented in tables 3 through 6 and amortizing the values over a 70 year lifetime in which an individual is exposed to vinclozolin 180 times per year (depending upon the job) over a 35 year working duration. [Note: The Agency does not anticipate that this is a common exposure scenario and as such has completed these calculations for only a selected few exposure scenarios in floriculture where exposures of this duration are anticipated.]

- **Table 16: Occupational Cancer Risks Attributable To Combined Dermal And Inhalation Exposures (180 annual exposure days)** Presents the cancer risks for individuals who are exposed to vinclozolin over an extended duration of exposure (i.e., 180 days).

Tables 1 through 6 of Appendix A illustrate how the calculations were performed to define the noncancer and cancer risks (i.e., MOEs) for vinclozolin handlers. The exposure data and exposure factors represent the best sources of data currently available to the Agency for completing these kinds of assessments. For example, maximum application rates were derived directly from vinclozolin labels. The recent use and usage report was also used to define average application rates as well as the annual frequency of application rates per crop. Exposure factors (e.g., body weight, amount treated per day, protection factors, etc.) are all standard values that have been used by the Agency over several years and are derived from peer reviewed sources whenever possible (e.g., Exposure Factors Handbook) and the PHED unit exposure values are the best available estimates of exposure. Some PHED unit exposure values are high quality while others represent low quality, but the best available, data. Tables 7 and 8 provide summaries of the MOE values calculated for each route of exposure, dermal and inhalation, respectively, in the risk assessment. Tables 9 through 11 provide the information that are the key to interpreting the overall results of the risk assessment because they contain the overall risks calculated using several combinations of personal protection for each exposure duration considered (e.g., short-/intermediate-term MOEs are presented in Table 9). Table 12 presents the ADDs that are a required element in the calculation of cancer risks using the linear, low-dose extrapolation method (i.e., Q_1*). The ADDs have been calculated using the absorbed dose levels presented in Tables 3 through 6. It is Agency policy when completing cancer risk assessments to consider different populations of individuals that might be exposed differently over a working lifetime. As such, the Agency has assessed this exposure pattern for individuals exposed over 90 day intervals in Tables 13 and 14. Table 13 contains the LADDs for that population while the cancer risks are presented in Table 14. Cancer risks are presented for a variety of levels of personal protection analogous to the noncancer risk results. The Agency also believes that there are individuals who can be exposed virtually every working day, so an exposure pattern for individuals exposed over 180 days intervals has been assessed in Tables 15 and 16. Table 15 contains the LADDs for that population while the cancer risks are presented in Table 16.

When protective measures are used to reduce risks it is appropriate to consider how each method will reduce the associated risks (e.g., gloves will reduce risks from dermal exposures by 90 percent based on the Agency protection factor for gloves). This is particularly important when route-specific (how the chemical enters the body) toxicity data are available, as is now the case for vinclozolin, because it allows for more flexibility in the risk management process (information presented in Appendix A/Tables 7 & 8). In addition, it is necessary to consider the combined risks for each scenario so that the risk management decision can be protective in an overall manner and also be based on the minimum level of personal protection from dermal and inhalation exposures. This is the key element in the risk assessment. The combined risks calculated for vinclozolin handlers are summarized below (Appendix A/Tables 9 through 11).

The risks are summarized based on the specific markets for vinclozolin use and the lowest level of personal protection where the Agency has no concern. The level of concern for all non-cancer occupational assessments is established by an uncertainty factor of 100 for all exposure durations and as > $1x10^{-6}$ for occupational cancer risks (1×10^{-4} with mitigation) calculated using the Q_1* (linear low dose extrapolation) approach. No level of concern has been established for the cancer MOEs that were calculated. These values are presented in conjunction with the other cancer risks for informational purposes and to provide for a more informed risk management decision. [Note: Each analysis below is based on the minimum level of personal protection required to achieve a level of no concern.]

For Occupational Treatments on Ornamental Use Sites:

(1a) mixing/loading dry flowables for aerial applications to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Aerial applications are considered unlikely by the Agency. In order to be protective, the Agency considered a treatment scenario of 350 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (MOE = 1154) with the use of engineering controls. [Note: If a more typical daily application acreage of 50 acres per day is considered for this scenario, MOEs would exceed 100 at the baseline level of personal protection.] Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not thought to occur for this scenario. As such, these risk values were not calculated for this scenario.

(1b) mixing/loading dry flowables for airblast applications to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Airblast applications are considered unlikely by the Agency, but to be protective the Agency considered a treatment scenario of 40 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 200) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not thought to occur for this scenario. As such, these risk values were not calculated for this scenario.

(1c) mixing/loading dry flowables for groundboom applications to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Groundboom applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 80 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs = 100 at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(1d) mixing/loading dry flowables for high-pressure handwand applications to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). High pressure handwand applications are considered a likely application method by the Agency. In order to be protective and informative the Agency considered two treatment scenarios of 1000 gallons/day coupled with application rates of 0.0025 lb ai/gallon and 0.005 lb ai/gallon. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 2100 and 4100, respectively) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(1e) mixing/loading dry flowables for dipping applications:

As a post-harvest cut flower dip: The available labels indicate "as a post-harvest dip, dip flower buds 3 to 4 seconds in a solution of 1.5 to 3 pounds per 100 gallons of water" (i.e., a solution concentration of up to 0.015 lb ai/gallon). Dipping applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 100 gallons/day coupled with an application rate of 0.015 lb ai/gallon. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 6900) at the baseline level of personal protection. In this scenario, exposure over an extended period and lifetime are thought to occur for a small segment of the user population. Therefore, chronic exposure MOEs and cancer risks (including MOEs) were calculated. When chronic dermal and inhalation exposures were combined, MOEs > 100 (approximately 3200) at the baseline level of personal protection. When cancer

MOEs were calculated using short-/intermediate-term dermal and inhalation exposures, MOEs also were >

100 (approximately 13,100) at the baseline level of personal protection. When cancer risks were calculated using the linear, low dose extrapolation approach, risks were 1.3 x 10^{-5} (90 days annual exposure) and 2.7 x 10^{-5} (180 days annual exposure) at the baseline level of personal protection even with the high number of annual use days considered in this assessment.

As a Bulbs and corm dip: The available labels indicate applications are to be made by dipping in a solution prepared by adding from 1 to 2 pounds per 100 gallons of water" (i.e., a solution concentration of up to 0.01 lb ai/gallon). See results for post-harvest cut flower dip above.

As a budwood and barefoot nursery stock dip: The available labels indicate applications are to be made by dipping in a solution prepared by adding 1.5 pounds per 100 gallons of water" (i.e., a solution concentration of 0.0075 lb ai/gallon). See results for post-harvest cut flower dip above.

(1f) mixing/loading dry flowables for thermal fogging applications to herbaceous and woody ornamentals (Thermal Fogging): The maximum single event application rate could not be established as the labels are inconclusive (even after several inquiries to BASF). Therefore, a risk assessment for this scenario could not be completed. The labels also indicated that "in a separate container prepare fogging solution of 19 fluid ounces of VK-11 carrier solution and 51 ounces of water. Then add the appropriate amount of Curalan."

(1g) mixing/loading dry flowables for low pressure/high volume turfgun applications: The maximum single event application rate is 1.35 ai/acre (i.e., 0.031 lb ai/1000 ft^2). All BASF labels, 7969-XX, have a maximum application rate of 1.35 lb ai/acre based on information contained in two 1998 letters to the Agency from A. Tobia of BASF to L. Rossi and J. Jones of EPA. Low pressure/high volume turfgun applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 5 acres/day coupled with an application rate of 1.35 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 1530) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(2a) mixing/loading liquid flowables for aerial applications to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Aerial applications are considered unlikely by the Agency but to be protective the Agency considered a treatment scenario of 350 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 176) with the use of engineering controls. [Note: If a more typical daily application acreage of 50 acres per day is considered for this scenario, MOEs would exceed 100 if gloves are used over and above the baseline level of personal protection.] Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not thought to occur for this scenario. As such, these risk values were not calculated for this scenario.

(2b) mixing/loading liquid flowables for airblast applications to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Airblast applications are considered unlikely by the Agency but to be protective the Agency considered a treatment scenario of 40 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 500) when a gloves are worn over and above the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(2c) mixing/loading liquid flowables for groundboom applications to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Groundboom applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 80 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 250) when gloves are worn over and above the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(2d) mixing/loading liquid flowables for high-pressure handwand applications to herbaceous

and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). High pressure handwand applications are considered a likely application method by the Agency. In order to be protective and informative the Agency considered two treatment scenarios of 1000 gallons/day coupled with application rates of 0.0025 lb ai/gallon and 0.005 lb ai/gallon. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 5100 and 10,000 respectively) when gloves are worn over and above the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(2e) mixing/loading liquid flowables for dipping applications:

As a post-harvest cut flower dip: The available labels indicate "as a post-harvest dip, dip flower buds 3 to 4 seconds in a solution of 1.5 to 3 pounds per 100 gallons of water" (i.e., a solution concentration of up to 0.015 lb ai/gallon). Dipping applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 100 gallons/day coupled with an application rate of 0.015 lb ai/gallon. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 160) at the baseline level of personal protection. In this scenario, exposure over an extended period and lifetime are expected to occur for a small segment of the user population. Therefore, chronic exposure MOEs and cancer risks (including MOEs) were calculated. When chronic dermal and inhalation exposures were combined, MOEs > 100 (approximately 8000) when gloves are worn over and above the baseline level of personal protection. Similarly, when cancer MOEs were calculated using short-/intermediate-term dermal and inhalation exposures, MOEs also were > 100 (approximately 32,600) when gloves are worn over and above the baseline level of personal protection. When cancer risks were calculated using the linear, low dose extrapolation approach, risks were 5.4×10^{-6} (90 days annual exposure) and 1.07×10^{-5} (180 days annual exposure) when gloves are worn over and above the baseline level of personal protection even with the high number of annual use days considered in this assessment.

As a Bulbs and corm dip: The available labels indicate applications are to be made by dipping in a solution prepared by adding from 1 to 2 pounds per 100 gallons of water" (i.e., a solution concentration of up to 0.01 lb ai/gallon). See results for post-harvest cut flower dip above.

As a budwood and barefoot nursery stock dip: The available labels indicate applications are to be made by dipping in a solution prepared by adding 1.5 pounds per 100 gallons of water" (i.e., a solution concentration of 0.0075 lb ai/gallon). See results for post-harvest cut flower dip above.

(2f) mixing/loading liquid flowables for thermal fogging applications to herbaceous and woody ornamentals (Thermal Fogging): The maximum single event application rate could not be established as the labels are inconclusive (even after several inquiries to BASF). Therefore, a risk assessment for this scenario could not be completed. The labels also indicated that “in a separate container prepare fogging solution of 19 fluid ounces of VK-11 carrier solution and 51 ounces of water. Then add the appropriate amount of Curalan.”

(2g) mixing/loading liquid flowables for low pressure/high volume turfgun applications: The maximum single event application rate is 1.35 ai/acre (i.e., 0.031 lb ai/1000 ft^2). All BASF labels, 7969-XX, have a maximum application rate of 1.35 lb ai/acre based on information contained in two 1998 letters to the Agency from A. Tobia of BASF to L. Rossi and J. Jones of EPA. Low pressure/high volume turfgun applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 5 acres/day coupled with an application rate of 1.35 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 3800) when gloves are worn over and above the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(3a) mixing/loading extruded granules for aerial and chemigation applications to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Aerial applications are considered unlikely by the Agency but to be protective the Agency considered a treatment scenario of 350 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 104) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(3b) mixing/loading extruded granules for airblast applications to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Airblast applications are considered unlikely by the Agency but to be protective the Agency considered a treatment scenario of 40 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 900) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(3c) mixing/loading extruded granules for groundboom applications to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Groundboom applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 80 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 450) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(3d) mixing/loading extruded granules for high-pressure handwand applications to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). High pressure handwand applications are considered a likely application method by the Agency. In order to be protective and informative the Agency considered two treatment scenarios of 1000 gallons/day coupled with application rates of 0.0025 lb ai/gallon and 0.005 lb ai/gallon. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 9400 and 18,900 respectively) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(3e) mixing/loading extruded granules for dipping applications:

As a post-harvest cut flower dip: The available labels indicate "as a post-harvest dip, dip flower buds 3 to 4 seconds in a solution of 1.5 to 3 pounds per 100 gallons of water" (i.e., a solution concentration of up to 0.015 lb ai/gallon). Dipping applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 100 gallons/day coupled with an application rate of 0.015 lb ai/gallon. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 31,400) at the baseline level of personal protection. In this scenario, exposure over an extended period and lifetime are expected to occur for a small segment of the user population. Therefore, chronic exposure MOEs and cancer risks (including MOEs) were calculated. When chronic dermal and inhalation exposures were combined, MOEs > 100 (approximately 14,600) at the baseline level of personal protection. Similarly, when cancer MOEs were calculated using short-/intermediate-term dermal and inhalation exposures, MOEs also were > 100 (approximately 59,900) at the baseline level of personal protection. When cancer risks were calculated using the linear, low dose extrapolation approach, risks were 2.9 x 10^{-6} (90 days annual exposure) and 5.85 x 10^{-6} (180 days annual exposure) at the baseline level of personal protection even with the high number of annual use days considered in this assessment.

As a Bulbs and corm dip: The available labels indicate applications are to be made by dipping in a solution prepared by adding from 1 to 2 pounds per 100 gallons of water" (i.e., a solution concentration of up to 0.01 lb ai/gallon). See results for post-harvest cut flower dip above.

As a budwood and barefoot nursery stock dip: The available labels indicate applications are to be made by dipping in a solution prepared by adding 1.5 pounds per 100 gallons of water" (i.e., a solution concentration of 0.0075 lb ai/gallon). See results for post-harvest cut flower dip above.

(3f) mixing/loading extruded granules for thermal fogging applications to herbaceous and woody ornamentals (Thermal Fogging): The maximum single event application rate could not be established as the labels are inconclusive (even after several inquiries to BASF). Therefore, a risk assessment for this scenario could not be completed. The labels also indicated that "in a separate container prepare fogging solution of 19 fluid ounces of VK-11 carrier solution and 51 ounces of water. Then add the appropriate amount of Curalan."

(3g) mixing/loading extruded granules for low pressure/high volume turfgun applications: The maximum single event application rate is 1.35 ai/acre (i.e., 0.031 lb ai/1000 ft^2). All BASF labels, 7969-XX, have a maximum application rate of 1.35 lb ai/acre based on information contained in two 1998 letters to the Agency from A. Tobia of BASF to L. Rossi and J. Jones of EPA. Low pressure/high volume turfgun applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 5 acres/day coupled with an application rate of 1.35 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 7000) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(4) applying sprays with an airblast sprayer to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Airblast applications are considered unlikely by the Agency but to be protective the Agency considered a treatment scenario of 40 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 660) when engineering controls are used (i.e., closed cabs). Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(5) applying sprays with a groundboom sprayer to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Groundboom applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 80 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 400) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario. [Note: The results of this risk analysis also reflect the risks associated with the use of vinclozolin on sodfarms if applications are completed using groundboom application equipment.]

(6) applying sprays with a fixed-wing aircraft (also accounts for helicopter applications) to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Aerial applications are considered unlikely by the Agency but to be protective the Agency considered a treatment scenario of 350 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 300) when engineering controls are used (i.e., closed cockpits or cabs are the commonly used aircraft equipment so no other levels of personal protection have been considered for this scenario). Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(7) application by thermal fogging in greenhouses to herbaceous and woody ornamentals (Thermal Fogging): The maximum single event application rate could not be established as the labels are inconclusive (even after several inquiries to BASF). Therefore, a risk assessment for this scenario could not be completed. The labels also indicated that "in a separate container prepare fogging solution of 19 fluid ounces of VK-11 carrier solution and 51 ounces of water. Then add the appropriate amount of Curalan."

(8) applying by dipping cut flowers, nurserystock, or bulbs and corm:

As a post-harvest cut flower dip: The available labels indicate "as a post-harvest dip, dip flower buds 3 to 4 seconds in a solution of 1.5 to 3 pounds per 100 gallons of water" (i.e., a solution concentration of up to 0.015 lb ai/gallon). No data were available to assess this scenario.

As a Bulbs and corm dip: The available labels indicate applications are to be made by dipping in a solution prepared by adding from 1 to 2 pounds per 100 gallons of water" (i.e., a solution concentration of up to 0.01 lb ai/gallon). No data were available to assess this scenario.

As a budwood and barefoot nursery stock dip: The available labels indicate applications are to be made by dipping in a solution prepared by adding 1.5 pounds per 100 gallons of water" (i.e., a solution concentration of 0.0075 lb ai/gallon). No data were available to assess this scenario.

(10) applying using a high-pressure handwand sprayer to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). High pressure handwand applications are considered a likely application method by the Agency. In order to be protective and informative the Agency considered two treatment scenarios of 1000 gallons/day coupled with application rates of 0.0025 lb ai/gallon and 0.005 lb ai/gallon. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 135) at the baseline level of personal protection for the low concentration application solution and were >100 (approximately 150) when gloves are worn over and above the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(11) applying using a low-pressure/high-volume turfgun sprayer: The maximum single event application rate is 1.35 ai/acre (i.e., 0.031 lb ai/1000 ft^2). All BASF labels, 7969-XX, have a maximum application rate of 1.35 lb ai/acre based on information contained in two 1998 letters to the Agency from A. Tobia of BASF to L. Rossi and J. Jones of EPA. Low pressure/high volume turfgun applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 5 acres/day coupled with an application rate of 1.35 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 136) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(12) mixing/loading/applying using a low-pressure handwand sprayer:

To herbaceous and woody ornamentals as a foliar spray: The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Low pressure handwand sprayer applications are considered a likely application method by the Agency. In order to be protective the Agency considered treatment scenarios of 40 gallons/day coupled with application rates of 0.0025 lb ai/gallon and 0.005 lb ai/gallon. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 6500 and 13,000 respectively) when gloves are worn over and above the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

As a post-harvest cut flower foliar spray: The available labels indicate that cut flowers are to be treated using a solution at a concentration of "1.5 to 3 pounds [end-use product] per 100 gallons of water" (i.e., a solution concentration of up to 0.015 lb ai/gallon). Applications are to be made "after grading and prior to cold storage." Low pressure handwand sprayer applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 40 gallons/day coupled with an application rate of 0.015 lb ai/gallon. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 2170) when gloves are worn over and above the baseline level of personal protection. In this scenario, exposure over an extended period and lifetime are expected to occur for a small segment of the user population. Therefore, chronic exposure MOEs and cancer risks (including MOEs) were calculated. When chronic dermal and inhalation exposures were combined, MOEs > 100 (approximately 1000) when gloves are worn over and above the baseline level of personal protection. Similarly, when cancer MOEs were calculated using short-/intermediate-term dermal and inhalation exposures, MOEs also were > 100 (approximately 1100) when gloves are worn over and above the baseline level of personal protection. When cancer risks were calculated using the linear, low dose extrapolation approach, risks were 4.2×10^{-5} (90 days annual exposure) and 8.5×10^{-5} (180 days annual exposure) when gloves were worn over and above the baseline level of personal protection even with the high number of annual use days considered in this assessment.

(13) mixing/loading/applying using a backpack sprayer:

To herbaceous and woody ornamentals as a foliar spray: The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Backpack sprayer applications are considered a likely application method by the Agency. In order to be protective the Agency considered treatment scenarios of 40 gallons/day coupled with application rates of 0.0025 lb ai/gallon and 0.005 lb ai/gallon. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 2700 and 1300 respectively) when gloves are worn over and above the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

As a post-harvest cut flower foliar spray: The available labels indicate that cut flowers are to be treated using a solution at a concentration of "1.5 to 3 pounds [end-use product] per 100 gallons of water" (i.e., a solution concentration of up to 0.015 lb ai/gallon). Applications are to be made "after grading and prior to cold storage." Backpack sprayer applications are considered a likely application method by the Agency. In order to be protective the Agency considered a treatment scenario of 40 gallons/day coupled with an application rate of 0.015 lb ai/gallon. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 450) when gloves are worn over and above the baseline level of personal protection. In this scenario, exposure over an extended period and lifetime are expected to occur for a small segment of the user population. Therefore, chronic exposure MOEs and cancer risks (including MOEs) were calculated. When chronic dermal and inhalation exposures were combined, MOEs > 100 (approximately 210) when gloves are worn over and above the baseline level of personal protection. Similarly, when cancer MOEs were calculated using short-/intermediate-term dermal and inhalation exposures, MOEs also were > 100 (approximately 870) when gloves are worn over and above the baseline level of personal protection. When cancer risks were calculated using the linear, low dose extrapolation approach, risks were never less than 1.0×10^{-4} (90 or 180 days annual exposure) at any level of personal protection considered. This result should be considered in the context of the likely exposed population is very small, the high number of annual use days considered, and that all calculated risks never exceeded approximately 4.0×10^{-4} for all levels of personal protection considered.

(14) flagging for aerial spray application to herbaceous and woody ornamentals (Foliar Spray): The maximum single event application rate ranges from 0.25 to 0.50 pounds of active ingredient per 100 gallons of spray solution (i.e., 0.0025 lb/gallon to 0.0050 lb/gallon). The available labels indicate "normally 2 to 6 gallons of spray make-up will cover 1000 ft^2 of foliage (i.e., 1.3 lb ai/acre based on 6 gallons per 1000 ft^2). Flagging for aerial applications is considered unlikely by the Agency but to be protective the Agency considered a treatment scenario of 350 acres/day coupled with an application rate of 1.3 lb ai/acre. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 127) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

<u>For Occupational Uses In Agriculture on Terrestrial Crops/Targets:</u>

(1a) mixing/loading dry flowables for aerial and chemigation applications:

To field crops including (canola, lettuce, onions, snapbeans): The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre on lettuce; from 0.75 to

1.0 pounds of active ingredient per acre for onions; from 0.33 to 0.45 pounds of active ingredient per acre for canola; and 0.5 pounds of active ingredient per acre for snapbeans. Typical application rates are 0.4 lb ai/acre for canola; 0.5 lb ai/acre for snapbeans and onions; and 0.8 lb ai/acre for lettuce. Aerial applications are considered likely by the Agency for some of these crops. In order to be protective the Agency considered a treatment scenario of 350 acres/day coupled with a range of application rates of 0.4 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 102) with the use of double layer clothing and gloves. [Note: If a more typical daily application acreage of 50 acres per day is considered for this scenario, MOEs would exceed 100 at the baseline level of personal protection.] At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 1500) with the use of engineering controls. [Note: If a more typical daily application acreage of 50 acres per day is considered for this scenario, MOEs would exceed 100 at the baseline level of personal protection.] Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. See the summary of results above for the field crops assessed in this scenario as the application rates and acreages would be anticipated to be similar for the field crops.

(1b) mixing/loading dry flowables for airblast applications:

To field crops including trellised snapbeans: The maximum single event application rate is 0.5 pounds of active ingredient per acre for snapbeans. The typical application rate is also anticipated to be 0.5 lb ai/acre for snapbeans. See results for raspberries at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar. It should be noted that this exposure scenario is unlikely but was considered by the Agency because it is plausible given current vinclozolin labeling.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. Airblast applications are considered likely by the Agency for raspberries. In order to be protective the Agency considered a treatment scenario of 40 acres/day coupled with a range of application rates of 0.5 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 517) at the baseline level of personal protection. At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 258) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To kiwi fruit trees (Section 24C label only): The maximum single event application rate is 1.0 pound of active ingredient per acre. The typical application rate is 0.9 lb ai/acre for kiwi. See results for raspberries at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar.

(1c) mixing/loading dry flowables for groundboom applications:

To field crops including (canola, lettuce, onions, snapbeans): The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre on lettuce; from 0.75 to 1.0 pounds of active ingredient per acre for onions; from 0.33 to 0.45 pounds of active ingredient per acre for canola; and 0.5 pounds of active ingredient per acre for snapbeans. Typical application rates are 0.4 lb ai/acre for canola; 0.5 lb ai/acre for snapbeans and onions; and 0.8 lb ai/acre for lettuce. Groundboom applications are considered likely by the Agency for field crops. In order to be protective the Agency considered a treatment scenario of 80 acres/day coupled with a range of application rates of 0.4 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 323) at the baseline level of personal protection. At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 129) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. See results for the field crops at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar.

(1d) mixing/loading dry flowables for greenhouse forcing tray applications to chicory/endive (Section 24C label only): During the forcing process, the maximum single event application rate is 1 gram of active ingredient in 3 liters of water per square meter of forcing tray surface area. Forcing tray applications are considered likely by the Agency for field crops chicory/endive propagation activities. In order to be protective the Agency considered a treatment scenario of 500 gallons/day coupled with an application rate of 1.0 lb ai/gallon. When short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 1050) with the use of engineering controls (i.e., water soluble packaging). Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

(2a) mixing/loading liquid flowables for aerial applications:

To field crops including (canola, lettuce, onions, snapbeans): The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre on lettuce; from 0.75 to 1.0 pounds of active ingredient per acre for onions; from 0.33 to 0.45 pounds of active ingredient per acre for canola; and 0.5 pounds of active ingredient per acre for snapbeans. Typical application rates are 0.4 lb ai/acre for canola; 0.5 lb ai/acre for snapbeans and onions; and 0.8 lb ai/acre for lettuce. Aerial applications are considered likely by the Agency for some of these crops. In order to be protective the Agency considered a treatment scenario of 350 acres/day coupled with a range of application rates of 0.4 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 184) when gloves were worn over and above the baseline level of personal protection. At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 107) when double layer clothing, gloves, and a PF5 respirator is used. [Note: If a more typical daily application acreage of 50 acres per day is considered for this scenario, MOEs would exceed 100 without the need for a respirator or the additional layer of clothing.] Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. See results for the field crops at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar.

(2b) mixing/loading liquid flowables for airblast applications:

To field crops including trellised snapbeans: The maximum single event application rate is 0.5 pounds of active ingredient per acre for snapbeans. The typical application rate is also anticipated to be 0.5 lb ai/acre for snapbeans. See results for raspberries at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar. It should be noted that this exposure scenario is unlikely but was considered by the Agency because it is plausible given current vinclozolin labeling.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. Airblast applications are considered likely by the Agency for raspberries. In order to be protective the Agency considered a treatment scenario of 40 acres/day coupled with a range of application rates of 0.5 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 1286) when gloves are worn over and above the baseline level of personal protection. At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 643) when gloves are worn over and above the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To kiwi fruit trees (Section 24C label only): The maximum single event application rate is 1.0 pound of active ingredient per acre. The typical application rate is 0.9 lb ai/acre for kiwi. See results for raspberries at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar.

(2c) mixing/loading liquid flowables for groundboom applications:

To field crops including (canola, lettuce, onions, snapbeans): The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre on lettuce; from 0.75 to 1.0 pounds of active ingredient per acre for onions; from 0.33 to 0.45 pounds of active ingredient per acre for canola; and 0.5 pounds of active ingredient per acre for snapbeans. Typical application rates are 0.4 lb ai/acre for canola; 0.5 lb ai/acre for snapbeans and onions; and 0.8 lb ai/acre for lettuce. Groundboom applications are considered likely by the Agency for field crops. In order to be protective the Agency considered a treatment scenario of 80 acres/day coupled with a range of application rates of 0.4 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 804) when gloves are worn over and above the baseline level of personal protection. At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 321) when gloves are worn over and above the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. See results for the field crops at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar.

(3a) mixing/loading extruded granules for aerial and chemigation applications:

To field crops including (canola, lettuce, onions, snapbeans): The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre on lettuce; from 0.75 to 1.0 pounds of active ingredient per acre for onions; from 0.33 to 0.45 pounds of active ingredient per acre for canola; and 0.5 pounds of active ingredient per acre for snapbeans. Typical application rates are 0.4 lb ai/acre for canola; 0.5 lb ai/acre for snapbeans and onions; and 0.8 lb ai/acre for lettuce. Aerial applications are considered likely by the Agency for some of these crops. In order to be protective the Agency considered a treatment scenario of 350 acres/day coupled with a range of application rates of 0.4 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 337) at the baseline level of personal protection. At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 135) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. See results for the field crops at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar.

(3b) mixing/loading extruded granules for airblast applications:

To field crops including trellised snapbeans: The maximum single event application rate is 0.5 pounds of active ingredient per acre for snapbeans. The typical application rate is also anticipated to be 0.5 lb ai/acre for snapbeans. See results for raspberries at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar. It should be noted that this exposure scenario is unlikely but was considered by the Agency because it is plausible given current vinclozolin labeling.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. Airblast applications are considered likely by the Agency for raspberries. In order to be protective the Agency considered a treatment scenario of 40 acres/day coupled with a range of application rates of 0.5 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 2358) at the baseline level of personal protection. At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 1179) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To kiwi fruit trees (Section 24C label only): The maximum single event application rate is 1.0 pound of active ingredient per acre. The typical application rate is 0.9 lb ai/acre for kiwi. See results for raspberries at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar.

(3c) mixing/loading extruded granules for groundboom applications:

To field crops including (canola, lettuce, onions, snapbeans): The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre on lettuce; from 0.75 to 1.0 pounds of active ingredient per acre for onions; from 0.33 to 0.45 pounds of active ingredient per acre for canola; and 0.5 pounds of active ingredient per acre for snapbeans. Typical application rates are 0.4 lb ai/acre for canola; 0.5 lb ai/acre for snapbeans and onions; and 0.8 lb ai/acre for lettuce. Groundboom applications are considered likely by the Agency for field crops. In order to be protective the Agency considered a treatment scenario of 80 acres/day coupled with a range of application rates of 0.4 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 1474) at the baseline level of personal protection. At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 590) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. See results for the field crops at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar.

(4) applying sprays with an airblast sprayer:

To field crops including trellised snapbeans: The maximum single event application rate is 0.5 pounds of active ingredient per acre for snapbeans. The typical application rate is also anticipated to be 0.5 lb ai/acre for snapbeans. See results for raspberries at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar. It should be noted that this exposure scenario is unlikely but was considered by the Agency because it is plausible given current vinclozolin labeling.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. Airblast applications are considered likely by the Agency for raspberries. In order to be protective the Agency considered a treatment scenario of 40 acres/day coupled with a range of application rates of 0.5 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 139) when gloves are worn over and above the baseline level of personal protection. At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 860) with the use of engineering controls (i.e., closed cabs). Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To kiwi fruit trees (Section 24C label only): The maximum single event application rate is 1.0 pound of active ingredient per acre. The typical application rate is 0.9 lb ai/acre for kiwi. See results for raspberries at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar.

(5) applying sprays with a groundboom sprayer:

To field crops including (canola, lettuce, onions, snapbeans): The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre on lettuce; from 0.75 to 1.0 pounds of active ingredient per acre for onions; from 0.33 to 0.45 pounds of active ingredient per acre for canola; and 0.5 pounds of active ingredient per acre for snapbeans. Typical application rates are 0.4 lb ai/acre for canola; 0.5 lb ai/acre for snapbeans and onions; and 0.8 lb ai/acre for lettuce. Groundboom applications are considered likely by the Agency for field crops. In order to be protective the Agency considered a treatment scenario of 80 acres/day coupled with a range of application rates of 0.4 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 1317) at the baseline level of personal protection. At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 527) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. See results for the field crops at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar.

(6) applying sprays with a fixed-wing aircraft (also accounts for helicopter applications):

To field crops including (canola, lettuce, onions, snapbeans): The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre on lettuce; from 0.75 to 1.0 pounds of active ingredient per acre for onions; from 0.33 to 0.45 pounds of active ingredient per acre for canola; and 0.5 pounds of active ingredient per acre for snapbeans. Typical application rates are 0.4 lb ai/acre for canola; 0.5 lb ai/acre for snapbeans and onions; and 0.8 lb ai/acre for lettuce. Aerial applications are considered likely by the Agency for some of these crops. In order to be protective the Agency considered a treatment scenario of 350 acres/day coupled with a range of application rates of 0.4 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 968) when engineering controls are used (i.e., closed cockpits or cabs are the commonly used aircraft equipment so no other levels of personal protection have been considered for this scenario). At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 387) when engineering controls are used (i.e., closed cockpits or cabs are the commonly used aircraft equipment so no other levels of personal protection have been considered for this scenario). Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. See results for the field crops at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar.

(9) applying to chicory/endive rootstock in forcing tray (Section 24C label only): During the forcing process, the maximum single event application rate is 1 gram of active ingredient in 3 liters of water per square meter of forcing tray surface area. No data were available to assess this scenario.

(12) mixing/loading/applying using a low-pressure handwand sprayer to chicory/endive prior to cold storage (Section 24C label only): For cold storage, the maximum single event application rate is 10 grams of active ingredient applied in 20 liters of water per metric ton of roots (i.e., 0.004 lb ai/gallon/metric ton of roots). Low pressure handwand sprayer applications are considered a likely application method by the Agency. In order to be protective the Agency considered treatment scenarios of 40 gallons/day coupled with application rates of 0.0025 lb ai/gallon and 0.005 lb ai/gallon (which is a similar, slightly higher rate for treatment of ornamentals). When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 6500 and 13,000 respectively) when gloves are worn over and above the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario. [Note: The differences in maximum application rate between ornamentals and the use on chicory/endive is insignificant because the risk numbers exceed the Agency's level of concern by such a wide margin.]

(13) mixing/loading/applying using a backpack sprayer to chicory/endive prior to cold storage (Section 24C label only): For cold storage, the maximum single event application rate is 10 grams of active ingredient applied in 20 liters of water per metric ton of roots (i.e., 0.004 lb ai/gallon/metric ton of roots). Backpack sprayer applications are considered a likely application method by the Agency. In order to be protective the Agency considered treatment scenarios of 40 gallons/day coupled with application rates of 0.0025 lb ai/gallon and 0.005 lb ai/gallon which are the application rates for ornamentals considered in this assessment (i.e., the results for the ornamental assessment are used also to address this scenario as the exposures and application rates are similar -- the results are not expected to significantly differ based on slight differences in application rates). When short-/intermediate-term dermal and inhalation exposures were combined, MOEs > 100 (approximately 1363 and 2727 respectively) when gloves are worn over and above the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario. [Note: The differences in maximum application rate between ornamentals and the use on chicory/endive is insignificant because the risk numbers exceed the Agency's level of concern by such a wide margin.]

(14) flagging for aerial spray application:

To field crops including (canola, lettuce, onions, snapbeans): The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre on lettuce; from 0.75 to 1.0 pounds of active ingredient per acre for onions; from 0.33 to 0.45 pounds of active ingredient per acre for canola; and 0.5 pounds of active ingredient per acre for snapbeans. Typical application rates are 0.4 lb ai/acre for canola; 0.5 lb ai/acre for snapbeans and onions; and 0.8 lb ai/acre for lettuce. Flagging for aerial applications are considered likely by the Agency for some of these crops. In order to be protective the Agency considered a treatment scenario of 350 acres/day coupled with a range of application rates of 0.4 to 1.0 lb ai/acre. At the typical application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 412) at the baseline level of personal protection. At the maximum application rate, when short-/intermediate-term dermal and inhalation exposures were combined, MOEs>100 (approximately 165) at the baseline level of personal protection. Chronic exposures or extended periods of exposure related to the development of cancer from vinclozolin exposure are not expected to occur for this scenario. As such, these risk values were not calculated for this scenario.

To raspberries: The maximum single event application rate ranges from 0.5 to 1.0 pounds of active ingredient per acre. The typical application rate is 0.6 lb ai/acre for raspberries. See results for the field crops at the typical rate assessed in this scenario as the application rate and acreage would be anticipated to be similar.

iii. Residential (Homeowner) Handler Risk Summary

A residential (homeowner) handler risk assessment was not completed for vinclozolin as there are no current products that are available for use by homeowners in the residential environment.

iv. Occupational Risks From Postapplication Exposures

As indicated in Section 2.b above, the Agency assessed risks for 9 postapplication exposure scenarios using the available chemical-specific dislodgeable foliar residue dissipation data, turf transferable residue data, and surrogate transfer coefficients for various activities of interest (e.g., harvesting crops or working in a greenhouse. Restricted entry intervals (REIs) are used by the Agency to regulate postapplication exposures because the Agency believes they are the most appropriate risk mitigation option for addressing these kinds of exposures. Requirements for additional clothing and personal protective equipment are not believed to be appropriate due to practical considerations (e.g., maintenance, enforcement, and other risk/stress factors such as heat exhaustion). Also, engineering controls are not considered practical in all but the most specialized scenarios because they are generally not available for mitigating postapplication risks. The data and calculations upon which this risk assessment is based upon are presented in Appendices D through G. Appendices D, E, and F contain the dislodgeable foliar residue data and turf transferable residue data that are the basis for the assessment (data for peaches, strawberries, and turf, respectively). These data have also been extensively analyzed from a kinetics perspective as indicated in Section 2.b. above. Predicted values calculated using each dissipation method and the associated linear regression analysis are also included in each Appendix. All of the risk calculations for occupational post-application exposures are included in Appendix G. The specifics of each of table included in Appendix G are described below as well as a summary of the risks for each exposure scenario.

- C **Table 1 : Residue Dissipation Data Used For Occupational Postapplication Risk Assessment** Presents the dislodgeable foliar residue data calculated using residue dissipation method 4 described in Section 2.b above (i.e., combining all data and using an exponential decay model) for peaches and strawberries used in the assessment. Also includes the turf transferable residue data measured in the study using each sampling method (i.e., California cloth roller data and aqueous wash method data) that have been calculated in the same manner.
- C **Table 2 : Exposure Inputs For Occupational Postapplication Risk Assessment** Contains each numerical input utilized in the calculation of the occupational postapplication risk values.
- C **Table 3: Postapplication Risks For Occupational Agricultural Scenario 1 (Scouting Canola, Onions, Lettuce)** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this exposure scenario.
- C **Table 4: Postapplication Risks For Occupational Agricultural Scenario 2 (Harvesting Lettuce)** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this exposure scenario.
- C **Table 5: Postapplication Risks For Occupational Agricultural Scenario 3 (Scouting/Harvesting Raspberries)** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this exposure scenario.
- C **Table 6: Postapplication Risks For Occupational Agricultural Scenario 4 (Harvesting Onions)** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this exposure scenario.
- C **Table 7: Postapplication Risks For Occupational Agricultural Scenario 4 (Harvesting Kiwi)** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this exposure scenario.
- C **Table 8: Postapplication Risks For Occupational Ornamental Scenario 1 (Mowing Turf)** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information

regarding all exposures represented by this scenario). This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this exposure scenario.

C **Table 9: Postapplication Risks For Occupational Ornamental Scenario 2 (Sorting/Packing Ornamentals)** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table includes MOEs calculated using all endpoints (i.e., short-/intermediate-term, chronic, and cancer) and cancer risks calculated using a Q_1* because chronic exposures and exposures of sufficient durations for cancer development are anticipated for this exposure scenario.

C **Table 10: Postapplication Risks For Occupational Ornamental Scenario 3 (Irrigating Ornamentals)** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table includes MOEs calculated using all endpoints (i.e., short-/intermediate-term, chronic, and cancer) and cancer risks calculated using a Q_1* because chronic exposures and exposures of sufficient durations for cancer development are anticipated for this exposure scenario.

C **Table 11: Postapplication Risks For Occupational Ornamental Scenario 4 (Turf Harvesting)** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this exposure scenario.

• **Table 12: Postapplication Risks For Occupational Ornamental Scenario 4 (Cutting Flowers With Standard TC)** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table includes MOEs calculated using all endpoints (i.e., short-/intermediate-term, chronic, and cancer) and cancer risks calculated using a Q_1* because chronic exposures and exposures of sufficient durations for cancer development are anticipated for this exposure scenario. The standard Agency transfer coefficient for cutting flowers and other high exposure work with ornamentals has been used to complete this assessment.

- **Table 13: Postapplication Risks For Occupational Ornamental Scenario 4 (Cutting Flowers With Literature TC)** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table includes MOEs calculated using all endpoints (i.e., short-/intermediate-term, chronic, and cancer) and cancer risks calculated using a Q_1* because chronic exposures and exposures of sufficient durations for cancer development are anticipated for this exposure scenario. The transfer coefficient defined in Brouwer et al, 1992 has been used to complete this assessment to provide for a more informed risk management decision.

The Agency manages postapplication occupational risks by defining the time it takes residues to dissipate to levels where risks do not exceed a level of concern. The amount of time for dissipation that is required is generally used by the Agency to establish Restricted Entry Intervals (REIs). The level of concern for this assessment is defined by the uncertainty factor of 100 for the short-/intermediate-term and chronic assessments. For the cancer risk assessment, risks that do not exceed $1x10^{-6}$ are generally considered as not exceeding a level of concern with the additional stipulation that risks at levels not exceeding $1x10^{-4}$ are also not a concern given that all attempts are made to further lower risk levels. The results of the assessment for each scenario considered are presented below:

<u>For Uses In Agriculture Resulting in Occupational Exposures:</u>

(1) adults scouting in canola, onions, lettuce, and other low row crops Risks for short-/intermediate-term exposures do not exceed the Agency's level of concern 9 days after application (MOE = 103). Chronic and cancer risks are not anticipated for this exposure scenario because it is believed that the exposures are not of sufficient duration.

(**2) adults harvesting lettuce** Risks for short-/intermediate-term exposures do not exceed the Agency's level of concern 21 days after application (MOE = 106). Chronic and cancer risks are not anticipated for this exposure scenario because it is believed that the exposures are not of sufficient duration.

(**3) adults scouting raspberries, and snapbeans as well as harvesting raspberries and low growing snapbeans** Risks for short-/intermediate-term exposures do not exceed the Agency's level of concern 27 days after application (MOE = 105). Chronic and cancer risks are not anticipated for this exposure scenario because it is believed that the exposures are not of sufficient duration.

(4) adults harvesting onions, kiwi, and trellised snapbeans Risks for short-/intermediate-term exposures do not exceed the Agency's level of concern 38 days after application (MOE = 100) for the onion harvesting scenario and 25 days after application (MOE = 105) for the kiwi harvesting scenario. The risks are different for the two scenarios because different dislodgeble foliar residue data have been used to consider the differences in application methods. The kiwi assessment was completed using peach data that were based on airblast application while the onion assessment was based on the use of the strawberry data that were based on the groundboom application method. Chronic and cancer risks are not anticipated for this exposure scenario because it is believed that the exposures are not of sufficient duration.

For Uses On Ornamentals Resulting in Occupational Exposures:

(1) adults mowing and maintaining treated turf Risks for short-/intermediate-term exposures do not exceed the Agency's level of concern on the day of application (MOE = 1705). Chronic and cancer risks are not anticipated for this exposure scenario because it is believed that the exposures are not of sufficient duration.

(2) adults sorting and packing ornamentals in a greenhouse Risks for short-/intermediate-term exposures do not exceed the Agency's level of concern for 21 days after application (MOE = 105). Chronic exposures do not exceed the Agency's level of concern for 31 days after application (MOE = 107). Cancer risks are never < $1x10^{-4}$ even 50 days after application. The results of the cancer risk assessment should be considered in conjunction with the input factors used to calculate the risks (e.g., a high frequency of exposure required for the cancer mechanism) and that these factors likely represent a very small segment of the exposed population. Cancer MOEs are presented for risk characterization purposes, at 50 days after application, the MOE is 1930.

(3) adults irrigating ornamentals Risks for short-/intermediate-term exposures do not exceed the Agency's level of concern until 27 days after application (MOE = 105). Chronic exposures do not exceed the Agency's level of concern for 37 days after application (MOE = 107). Cancer risks are never < $1x10^{-4}$ even 50 days after application. The results of the cancer risk assessment should be considered in conjunction with the input factors used to calculate the risks (e.g., a high frequency of exposure required for the cancer mechanism) and that these factors likely represent a very small segment of the exposed population. Cancer MOEs are presented for risk characterization purposes, at 50 days after application, the MOE is 1207.

(4) adults harvesting or placing sod Risks for short-/intermediate-term exposures do not exceed the Agency's level of concern until 5 days after application (MOE = 116). Chronic and cancer risks are not anticipated for this exposure scenario because it is believed that the exposures are not of sufficient duration.

(4) adults cutting flowers in a greenhouse When the standard transfer coefficient is used, risks for short-/intermediate-term exposures do not exceed the Agency's level of concern until 39 days after application (MOE = 107). Chronic exposures do not exceed the Agency's level of concern for 48 days after application (MOE = 101). Cancer risks are never < $1x10^{-4}$ even 50 days after application. The results of the cancer risk assessment should be considered in conjunction with the input factors used to calculate the risks (e.g., a high frequency of exposure required for the cancer mechanism) and that these factors likely represent a very small segment of the exposed population. Cancer MOEs are presented for risk characterization purposes, at 50 days after application, the MOE is 483. When the calculations are based on the Brouwer transfer coefficient value (i.e., approximately ½ of the Agency standard) the risks are reduced but this calculation still predicts an long duration before the short-/intermediate-term exposures do not exceed the Agency's level of concern (i.e., 30 days after application (MOE = 107). Likewise, chronic exposures do not exceed the Agency's level of concern for 39 days after application (MOE = 100). Cancer risks were also similar in that they were never < $1x10^{-4}$ even 50 days after application. The results of the cancer risk assessment should be considered in conjunction with the input factors used to calculate the risks (e.g., a high frequency of exposure required for the cancer mechanism) and that these factors likely represent a very small segment of the exposed population. Cancer MOEs are presented for risk characterization purposes, at 50 days after application, the MOE is 966.

(5) adults reentering fogged greenhouses for aeration of the facility An inhalation assessment only qualitatively assessed as similar assessment for completion of fogging activities completed above for handlers also applies to this scenario (see Section 2.b above).

v. Residential Risks From Postapplication Exposures

The use of a Restricted Entry Interval (REI) is not an appropriate method of risk mitigation for residential use chemicals and, essentially, for all exposure scenarios where there is the potential for unrestricted general population exposures. As a result, the approach used to evaluate residential risks is to consider exposures immediately after application as these represent higher exposures and risks. No chronic or cancer risks for adults or toddlers were considered in the residential assessment because it is believed that the residential exposure pattern is of sufficient duration for either type of exposure to be a concern to the Agency.

Residential risks were assessed for both adults and toddlers based on guidance provided in the *SOPs For Residential Exposure Assessment* and the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines (7/24/97 Version)* and the available chemical-specific data. The data and calculations upon which this risk assessment is based upon are presented in Appendices F and H. Appendices F contains the turf transferable residue data that are the basis for the assessment. These data have also been extensively analyzed from a kinetics perspective as indicated in Section 2.b. above. Predicted values calculated using each dissipation method and the associated linear regression analysis are also included Appendix F. All of the risk calculations for occupational post-application exposures are included in Appendix H. The specifics of each of table included in Appendix H are described below as well as a summary of the risks for each exposure scenario.

- **Table 1 : Residue Dissipation Data Used For Residential Postapplication Risk Assessment** Presents the turf transferable residue data calculated using residue dissipation method 4 described in Section 2.b above for each sampling method (i.e., California cloth roller data and aqueous wash method data) that have been calculated in the same manner.

- **Table 2 : Exposure Inputs For Residential Postapplication Risk Assessment** Contains each numerical input utilized in the calculation of the residential postapplication risk values.

- **Table 3: Postapplication Risks For Residential Scenario 1 (Adults Golfing)** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this exposure scenario.

C **Table 4: Postapplication Risks From Toddler Dermal Exposure For Residential Scenario 2** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this scenario.

• **Table 5: Postapplication Risks From Toddler Hand To Mouth Exposure For Residential Scenario 2** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this exposure scenario.

C **Table 6: Postapplication Risks From Toddler Object To Mouth Exposure For Residential Scenario 2** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this exposure scenario.

C **Table 7: Postapplication Risks From Toddler Soil Ingestion Exposure For Residential Scenario 2** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario). This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this exposure scenario.

C **Table 8: Postapplication Risks From Aggregate Toddler Exposures For Residential Scenario 2** Presents the risks calculated for this exposure scenario (see Section 2.b.iv for further information regarding all exposures represented by this scenario) for each exposure pathway considered and for aggregate exposures. This table only includes MOEs calculated using the short-/intermediate-term endpoint because chronic exposures and exposures of sufficient durations for cancer development are not anticipated for this exposure scenario.

As indicated above, the use of an REI as a mitigation tool in residential settings is not considered appropriate by the Agency because it is not believed that an administrative mitigation measure like the REI is applicable to the general public. Therefore, the approach used by the Agency to typically manage the risks of chemicals used in the residential environment attributable to post-application exposure is to determine if their use is acceptable on the day of application. This is the case for the golfer component of the risk assessment for vinclozolin. The basis for the sodfarm/toddler exposure scenario for vinclozolin however is somewhat different in that the objective of the assessment was to define the amount of time required after application on a sodfarm that is required for the material to dissipate prior to placing treated sod in a residential environment where infants and toddlers can be exposed (i.e., an REI approach has been used based on toddler exposures to define this interval). The level of concern for each of these assessments is defined by the uncertainty factor of 1000 for the short-/intermediate-term assessments (i.e., FQPA 10x uncertainty factor has been retained in this case). Chronic exposures and exposures of sufficient duration for cancer development are not anticipated in any of these scenarios. The results of the assessment for each scenario considered are presented below:

(1) adults golfing Risks for short-/intermediate-term exposures do not exceed the Agency's level of concern even on the day of application (MOE = 6819). Chronic and cancer risks are not anticipated for this exposure scenario because it is believed that the exposures are not of sufficient duration. [Note: The Agency has not yet developed a policy to address the exposures of youth who golf. It is, however, expected that these risks would not exceed the Agency's level of concern on the day of application because it is unlikely that these exposures would differ from the exposures of adult golfers by over a factor of 6.]

(2) toddlers engaged in heavy play on turf On the day of application, aggregate risks for short-/intermediate-term exposures exceed the Agency's level of concern (MOE = 33). Aggregate risks do not exceed the Agency's level of concern until 24 days after application (MOE = 1095). If the Agency allows for two days of time for sod in commerce (i.e., for harvesting, shipment, and placement), sod harvesting should not occur until 22 days after application in order to prevent risks in a residential environment for infants and toddlers from exceeding the Agency's level of concern. The MOEs calculated for each exposure pathway considered are summarized in the table below for the day of application as well as 22 and 24 days after application.

Days After Application	MOEs				
	Dermal	Hand to Mouth	Object to Mouth	Soil Ingestion	Aggregate
0	78	59	1882	73909	33
22	6476	987	31584	1240501	833
24	9675	1276	40816	1603067	1096

Chronic and cancer risks are not anticipated for this exposure scenario because it is believed that the exposures are not of sufficient duration.

vi. Incident reports

The incident report completed for this assessment is not included in this document. The report has been developed under a separate memo by Dr. Virginia Dobozy in 1996 of the Office of Pesticide Programs. This report as well as the results of this risk assessment are considered in the overall risk assessment for vinclozolin.

vii. Overall risk summary

Based on the assessment of various exposure scenarios, the Agency has some risk concerns over the use of vinclozolin in both the agricultural and ornamental/floriculture marketplaces. When short-/intermediate-term occupational exposures are considered for handlers, risks in all exposure scenarios do not exceed the Agency's level of concern for both the agricultural marketplace and in the ornamental/floriculture marketplace (MOEs range from just over 100 to >10,000 depending upon the use scenario and level of personal protection). This result is based on requiring different levels of personal protection for each exposure scenario considered. Some low use/low exposure scenarios do not exceed the Agency's level of concern at the baseline level of personal protection which entails the use of normal work clothing represented by long pants and a long-sleeved shirt (e.g., mixing/loading granules for airblast application to raspberries). In other cases, however, more extensive personal protection is required such as the use of gloves, additional clothing, respirators, or engineering controls such as closed tractor cabs or water soluble packaging for solid formulations. Chronic occupational handler exposure scenarios were only considered for a very limited number of uses that are allowable in the ornamental/floriculture marketplace (e.g., foliar spray applied to cut flowers such as roses prior to storage/shipment). The risks in all of these exposure scenarios do not exceed the Agency's level of concern if chemical-resistant gloves are worn in addition to long pants and long-sleeved shirts during the application process (MOEs range from 212 to >10,000). For all occupational handler scenarios considered in the cancer risk assessment, MOEs ranged from approximately 20 to approximately 60, 000 at the baseline level of personal protection (i.e., long-sleeved shirts and long-pants only). At the most appropriate maximum levels of personal protection (i.e., engineering controls or double layer clothing, gloves, and respirator -- depending upon scenario), MOEs ranged from approximately 1400 to 5900 for the handheld application methods and from approximately 101,000 to 2.9M when water soluble packaging was considered for preparing dipping solutions. Population-based cancer risk estimates for all scenarios considered were less than $1x10^{-4}$ (indicating that the exposure did not exceed the Agency's level of concern) for all scenarios considered and in many cases were less than $1x10^{-6}$ depending upon the level of personal protection upon which the assessment is based. The only scenario for which cancer risks exceeded the Agency's level of concern for all levels of personal protection considered was for backpack sprayers when used to treat cut flowers with a foliar spray. This pattern was reflected in the results regardless of the annual exposure frequency considered in the assessment (i.e., a total of 90 days and a total of 180 days annual exposure were considered). The results of the risk assessment for handlers should be considered in the context that the vast majority of occupational vinclozolin handler exposures are thought to be of a short-/intermediate-term nature by the Agency. Therefore, it is believed that exposures do not exceed the Agency's level of concern for the vast majority of vinclozolin handler exposures.

The majority of concerns that Agency has over the use of vinclozolin stem from the occupational postapplication exposures considered in this assessment. Postapplication risks are mitigated by the Agency using an administrative mitigation measure which is referred to as the Restricted Entry Interval (REI) which represents the amount of time required for residues to dissipate in treated areas prior to beginning a job or task in that area with accompanying exposures that do not exceed the Agency's level of risk concern (e.g., an uncertainty factor of 100 for noncancer occupational risk assessments). For most of the uses in agriculture, risks do not exceed the Agency's level of concern within 30 days after application. [Note: All risks in agriculture are considered to be short-/intermediate-term in duration as with the agricultural handler scenarios.] For activities in low row crops such as scouting canola or lettuce the Agency believes that reentry into treated areas can occur (i.e., risks do not exceed the Agency's level of concern) 9 days after application. The Agency also believes that reentry can occur 21 days after application for activities such as harvesting lettuce, after 25 days for harvesting kiwi, and after 27 days for scouting and harvesting raspberries and low-growing snapbeans. The only occupational scenarios in agriculture where postapplication risks exceeded the Agency's level of concern for more than 30 days after application was for hand harvesting of onions and trellised snapbeans (38 days are required) which are believed by the Agency to be plausible, yet not a very common practice in agriculture.

The occupational postapplication risks for the ornamental/floriculture marketplace included a short-/intermediate-term, chronic, and cancer risk assessment. Short-/intermediate-term exposure calculations were completed for all scenarios while an assessment for chronic exposures and exposures of sufficient duration to cause cancer were only completed for a select number of scenarios. When short-/intermediate-term exposures are considered, risks for most uses do not exceed the Agency's level of concern within 30 days after application. For example, the Agency believes that mowing and maintaining treated turf can occur on the same day as application. The Agency also believes that reentry can occur 21 days after application for activities such as sorting and packing ornamentals in a greenhouse, after 27 days when irrigating ornamentals, and after 5 days for harvesting or placing sod. The only occupational scenario where postapplication risks exceeded the Agency's level of concern for more than 30 days after application was for cutting flowers in a greenhouse where 30 to 39 days were required for exposures not to exceed the Agency's level of concern. Chronic exposures were only considered for certain tasks associated with the production of ornamentals in a greenhouse. In all cases, the durations required for entry into a previously treated area was extended compared to the short-/intermediate-term assessment. When exposures are of a chronic duration, the Agency believes that reentry can occur 31 days after application for activities such as sorting and packing ornamentals in a greenhouse, after 37 days when irrigating ornamentals, and 39 to 48 days for cutting flowers in a greenhouse. For the postapplication cancer risk assessment, a maximum of 50 days after application was considered because durations longer than 50 days far surpass any logical proposal for establishing a viable REI. Given this premise, population-based cancer risks still exceed the Agency's level of concern even at 50 days after application for all activities considered including sorting/packing, irrigation, and cutting flowers (i.e., all risks were > $1x10^{-4}$ for all scenarios considered even 50 days after application). Likewise, when cancer MOE values were calculated 50 days after application, these values were all <2000 for the same scenarios. As with the handler risks summarized above, the results of the risk assessment for postapplication workers in the ornamental/floriculture marketplace should be considered in the context that the vast majority of these exposures are thought to be of a short-/intermediate-term nature by the Agency. Therefore, it is believed that the results of the short-/intermediate-term risk assessment would be protective for mitigating most occupational postapplication risks.

Postapplication risks to the general population were only considered for golfers and for toddlers on sodfarm turf (in order to establish the amount of time required after application required for residue dissipation prior to harvest). All of these exposures are considered to be of a short-/intermediate-term nature by the Agency. Adult golfer exposures did not exceed the Agency's level of concern (i.e., an uncertainty factor of 1000) even on the day of application (MOE = 6800). Likewise, given the magnitude of the MOE for adults, the Agency also does not believe that risks for child golfers would exceed the level of concern. The aggregate MOE for toddlers on sodfarm turf (which represents an upper bound exposure that includes dermal and nondietary ingestion pathways) is 33 on the day of application. Risks do not exceed the Agency's level of concern until 24 days after application (MOE = 1096). If 2 days of transit time are allowed for sod harvest and placement, then treated sod cannot be harvested and placed into a residential environment for at least 22 days after application.

This assessment reflects the Agency's current approaches for completing residential exposure assessments based on the guidance provided in the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines*, *Group B-Postapplication Exposure Monitoring Test Guidelines (7/24/97 Version)*, the *Draft: Standard Operating Procedures (SOPs) for Residential Exposure Assessment (12/11/97 Version)*, and the *Overview of Issues Related to the Standard Operating Procedures for Residential ExposureAssessment* presented at the September 1999 meeting of the FIFRA Scientific Advisory Panel (SAP). The Agency is, however, currently in the process of revising its guidance for completing these types of assessments. Modifications to this assessment shall be incorporated as updated guidance becomes available and it is feasible from a regulatory perspective. This will include expanding the scope of the residential exposure assessments by developing guidance for characterizing exposures from other sources already not addressed such as from spray drift; residential residue track-in; exposures to farmworker children; and exposures to children in schools.

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